

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1210—REGULATIONS UNDER THE FEDERAL IMPORT MILK ACT

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AUTHORITY: 21 U.S.C. 141–149.

SOURCE: 38 FR 32104, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For Animal and Plant Health Inspection Service regulations concerning tubercular cattle, see 9 CFR parts 50 and 77. For Animal and Plant Health Inspection Service regulations, see 9 CFR chapter I. For customs regulations concerning importation of milk and cream, see 19 CFR 12.7. For regulations of the Agricultural Marketing Service (Marketing Agreements and Orders) covering marketing areas for milk, see 7 CFR chapter X.

Subpart A—General Provisions

§ 1210.1 Authority.

For the purposes of the regulations in this part the act (44 Stat. 1101; 21 U.S.C. 141–149) “To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health” shall be known and referred to as “the Federal Import Milk Act.”

§ 1210.2 Scope of act.

The provisions of the act apply to all milk and cream offered for import into the continental United States.

§ 1210.3 Definitions.

(a) *Secretary*. Secretary means the Secretary of Health and Human Services.

(b) *Commissioner*. Commissioner means the Commissioner of Food and Drugs.

(c) *Milk*. For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

(d) *Condensed milk*. Condensed milk, as the term is used in section 3, paragraph 2, of the Federal Import Milk Act, includes evaporated milk in the manufacture of which sterilization of the milk and cream is a necessary and usual process; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in section 3, paragraph 3, of the Federal Import Milk Act, means sweetened condensed milk.

(e) *Sweetened condensed milk*. Sweetened condensed milk conforms to the definition and standard of identity for

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such food as set out in § 131.120 of this chapter.

(f) *Evaporated milk.* Evaporated milk conforms to the definition and standard of identity for such food as set out in § 131.130 of this chapter.

(g) *Cream.* Cream is that portion of the milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. (See §§ 131.150 through 131.157 of this chapter).

(h) *Pasteurization.* Pasteurization is the process of heating every particle of milk or cream to at least 143 °F., and holding it at such temperature continuously for at least 30 minutes, or to at least 161 °F., and holding it at such temperature continuously for at least 15 seconds.

(i) *Shipper.* A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

[38 FR 32104, Nov. 20, 1973, as amended at 42 FR 14091, Mar. 15, 1977]

Subpart B—Inspection and Testing

§ 1210.10 Availability for examination and inspection.

Dairy farms and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

§ 1210.11 Sanitary inspection of dairy farms.

The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms in the form prescribed by the Secretary.

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§ 1210.12 Physical examination of cows.

(a) Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within one year previous to the time of the importation.

(b) The result of the physical examination shall be set forth in the form prescribed by the Secretary.

§ 1210.13 Tuberculin test.

(a) Except as provided in § 1210.27 any and all animals in herds producing milk or cream which is to be shipped or transported raw into the United States shall be free from tuberculosis, as determined by a tuberculin test applied by an official veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced. Such test shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within 1 year previous to the time of the importation. All animals showing positive or suspicious reactions to the tuberculin test must be permanently removed from the herd.

(b) The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Secretary.

§ 1210.14 Sanitary inspection of plants.

The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points according to the methods for scoring as provided by the score card for sanitary inspection of such plants in the form prescribed by the Secretary.

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§ 1210.15 Pasteurization; equipment and methods.

All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurization machinery of a type easily cleaned and of sanitary construction capable of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate time and temperature recording devices, which shall be kept at all times in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 2 years unless within that period they have been examined and released by such authorized agents as are designated by the Secretary.

§ 1210.16 Method of bacterial count.

The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

§ 1210.17 Authority to sample and inspect.

Inspectors engaged in the enforcement of the Federal Import Milk Act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.

§ 1210.18 Scoring.

Scoring of sanitary conditions required by §§ 1210.11, 1210.14 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

Subpart C—Permit Control

§ 1210.20 Application for permit.

Application for a permit to ship or transport milk or cream into the United States shall be made by the ac-

tual shipper upon forms prescribed by the Secretary. The request for forms of applications for permits should be addressed to Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

§ 1210.21 Permit number.

Each permit issued under the Federal Import Milk Act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

§ 1210.22 Form of tag.

Each container of milk or cream shipped or transported into the United States by such permittee shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

Product _____
(State whether raw milk, pasteurized milk, raw cream, or pasteurized cream.)
Permit number _____
Federal Import Milk Act, Department of Health and Human Services.
Shipper _____
Address of shipper _____

Provided, That in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if sealed, may be tagged with the above tag, which should, in addition, show the number of containers and quantity of contents of each.

§ 1210.23 Permits granted on certificates.

In the discretion of the Secretary, a permit may be granted on a duly certified statement signed by a duly accredited official of an authorized department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Secretary, and shall have attached thereto, as a part thereof, signed copies of reports prescribed by §§ 1210.12, 1230.13, and also by §§ 1210.11, 1210.14, as applicable. The necessary inspections and examinations upon which the reports are based

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shall be made by persons who are acting under the direct supervision of the certifying official.

§ 1210.24 Temporary permits.

A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the Federal Import Milk Act. Temporary permits shall be valid until the Secretary shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act have been complied with.

§ 1210.25 Permits for pasteurized milk or cream.

Permits to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11, 1210.12, 1210.14, as applicable.

§ 1210.26 Permits for raw milk or cream.

Except as provided in § 1210.27, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 1, 2, and 3 of section 2 of the Federal Import Milk Act, §§ 1210.11 to 1210.14 as applicable.

§ 1210.27 Permits waiving clauses 2 and 5, section 2 of the Federal Import Milk Act.

A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the Federal Import Milk Act when the shipper is an operator of a creamery or condensery, or is a producer shipping or transporting to a creamery or condensery and the creamery or condensery is located in the United States within a radius of 20 miles of the point of production of such milk, and the milk, prior to its sale, use, or disposal, is pasteurized, condensed, or evaporated.

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§ 1210.28 Permits waiving clause 4, section 2 of the Federal Import Milk Act.

The Secretary, in his discretion, will issue to a shipper who is an operator of a condensery a permit waiving the requirements of clause 4, of section 2 of the Federal Import Milk Act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensery is located within a radius of 15 miles of the point of production of the milk and cream and such milk and cream are to be sterilized in the manufacture of condensed milk.

Subpart D—Hearings

§ 1210.30 Hearing procedure for permit denial, suspension, and revocation.

Any person who contests denial, suspension, or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to subpart F of part 16 of this chapter.

[41 FR 48269, Nov. 2, 1976, as amended at 42 FR 15676, Mar. 22, 1977]

§ 1210.31 Hearing before prosecution.

Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

[41 FR 48269, Nov. 2, 1976]

PART 1230—REGULATIONS UNDER THE FEDERAL CAUSTIC POISON ACT

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AUTHORITY: 15 U.S.C. 1261–1276.

CROSS REFERENCES: For regulations relating to invoices, entry, and assessment of duties, see 19 CFR parts 141, 142, 143, 151, 152. For regulations regarding the examination, classification, and disposition of foods, drugs, devices, cosmetics, insecticides, fungicides, and caustic or corrosive substances, see 19 CFR part 12. For regulations relating to consular invoices, and documentation of merchandise, see 22 CFR parts 91 and 92.

SOURCE: 38 FR 32110, Nov. 20, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1230.2 Scope of the act.

The provisions of the act apply to any container which has been shipped or delivered for shipment in interstate or foreign commerce, as defined in section 2(c) of the act (44 Stat. 1407; 15 U.S.C. 402) or which has been received from shipment in such commerce for

sale or exchange, or which is sold or offered for sale or held for sale or exchange in any Territory or possession or in the District of Columbia.

§ 1230.3 Definitions.

(a) The word *container* as used in the regulations in this part means a retail parcel, package, or container suitable for household use and employed exclusively to hold any dangerous caustic or corrosive substance defined in the act.

(b) The words *suitable for household use* mean and imply adaptability for ready or convenient handling in places where people dwell.

Subpart B—Labeling

§ 1230.10 Placement.

The label or sticker shall be so firmly attached to the container that it will remain thereon while the container is being used, and be so placed as readily to attract attention.

§ 1230.11 Required wording.

(a) The common name of the dangerous caustic or corrosive substance which shall appear on the label or sticker is the name given in section 2(a) of the act (44 Stat. 1406; 15 U.S.C. 402) or any other name commonly employed to designate and identify such substance.

(b) Preparations within the scope of the act bearing trade or fanciful names shall, in addition, be labeled with the common name of the dangerous caustic or corrosive substance contained therein and comply with all the other requirements of the act and of the regulations in this part.

§ 1230.12 Manufacturer; distributor.

If the name on the label or sticker is other than that of the manufacturer, it shall be qualified by such words as “packed for,” “packed by,” “sold by,” or “distributed by,” as the case may be, or by other appropriate expression.

§ 1230.13 Labeling of “poison”.

The following are styles of uncondensed Gothic capital letters 24-point (type face) size:

POISON

POISON

When letters of not less than 24-point size are required on a label in stating the word “poison” they must not be smaller than those above set forth.

§ 1230.14 Directions for treatment.

Except as provided in § 1230.16, the container shall bear in all cases upon the label or sticker thereof, immediately following the word “Poison,” directions for treatment in the case of internal personal injury; in addition, if the substance may cause external injury, directions for appropriate treatment shall be given. The directions shall prescribe such treatments for personal injury as are sanctioned by competent medical authority, and the materials called for by such directions shall be, whenever practicable, such as are usually available in the household.

§ 1230.15 Responsibility for labeling directions for treatment.

A person who receives from a manufacturer or wholesaler any container which under the conditions set forth in section 2(b)(4) of the act and § 1230.16 does not bear at the time of shipment directions for treatment in the case of personal injury must place such directions on the label or sticker if he offers such container for general sale or exchange.

§ 1230.16 Exemption from labeling directions for treatment.

Manufacturers and wholesalers only, at the time of shipment or delivery for shipment, are exempted from placing directions for treatment on the label or sticker of any container for other than household use, but in any event the information required by section 2(b) (1), (2), and (3) of the act (44 Stat. 1407; 15 U.S.C. 402) and the regulations in this part shall be given.

Subpart C—Guaranty

§ 1230.20 General guaranty.

In lieu of a particular guaranty for each lot of dangerous caustic or corrosive substances, a general continuing guaranty may be furnished by the guarantor to actual or prospective purchasers. The following are forms of continuing guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances to be sold to _____ are not misbranded within the meaning of the Federal Caustic Poison Act.

(Date)

(Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler) (§§ 1230.15, 1230.16):

The dangerous caustic or corrosive substance or substances in retail parcels, packages, or containers suitable for household use to be sold to _____ are for other than household use, and guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.

(Date)

(Signature and address of manufacturer or wholesaler)

§ 1230.21 Specific guaranty.

If a guaranty in respect to any specific lot of dangerous caustic or corrosive substances be given, it shall be incorporated in or attached to the bill of sale, invoice, or other schedule bearing the date and the name and quantity of the substance sold, and shall not appear on the label or package. The following are forms of specific guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) are not misbranded within the meaning of the Federal Caustic Poison Act.

(Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler (§§ 1230.15, 1230.16):

The dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) in retail parcels, packages, or containers suitable for household use are for other than household use and are guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.

(Name and address of manufacturer or wholesaler)

Subpart D—Administrative Procedures

§ 1230.30 Collection of samples.

Samples for examination by or under the direction and supervision of the Food and Drug Administration shall be collected by:

(a) An authorized agent in the employ of the Department of Health and Human Services;

(b) Any officer of any State, Territory, or possession, or of the District of Columbia, authorized by the Secretary of Health and Human Services.

§ 1230.31 Where samples may be collected.

Caustic or corrosive substances within the scope of this act (44 Stat. 1406; 15 U.S.C. 401–411) may be sampled wherever found.

§ 1230.32 Analyzing of samples.

Samples collected by an authorized agent shall be analyzed at the laboratory designated by the Food and Drug Administration. Only such samples as are collected in accordance with §§ 1230.30, 1230.31 may be analyzed by or under the direction and supervision of the Food and Drug Administration. Upon request one subdivision of the sample, if available, shall be delivered to the party or parties interested.

§ 1230.33 Investigations.

Authorized agents in the employ of the Department of Health and Human Services may make investigations, including the inspection of premises where dangerous caustic and corrosive substances subject to the act are manufactured, packed, stored, or held for sale or distribution, and make examinations of freight and other transportation records.

§ 1230.34 Analysis.

(a) The methods of examination or analysis employed shall be those prescribed by the Association of Official Agricultural Chemists, when applicable, provided, however, that any method of analysis or examination satisfactory to the Food and Drug Administration may be employed.

(b) All percentages stated in the definitions in section 2(a) of the Federal Caustic Poison Act shall be determined by weight.

§ 1230.35 Hearings.

Whenever it appears from the inspection, analysis, or test of any container that the provisions of section 3 or 6 of the Federal Caustic Poison Act (44 Stat. 1407, 1409; 15 U.S.C. 403, 406) have been violated and criminal proceedings are contemplated, notice shall be given to the party or parties against whom prosecution is under consideration and to other interested parties, and a date shall be fixed at which such party or parties may be heard. The hearing shall be held at the office of the Food and Drug Administration designated in the notice and shall be private and confined to questions of fact. The parties notified may present evidence, either oral or written, in person or by attorney, to show cause why the matter should not be referred for prosecution as a violation of the Federal Caustic Poison Act.

§ 1230.36 Hearings; when not provided for.

No hearing is provided for when the health, medical, or drug officer or agent of any State, Territory, or possession, or of the District of Columbia, acts under the authority contained in section 8 of the Federal Caustic Poison

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Act (44 Stat. 1409; 15 U.S.C. 408) in reporting a violation direct to the United States attorney.

§ 1230.37 Publication.

(a) After judgment of the court in any proceeding under the Federal Caustic Poison Act, notice shall be given by publication. Such notice shall include the findings of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health and Human Services may deem appropriate.

(b) This publication may be made in the form of a circular, notice, or bulletin, as the Secretary of Health and Human Services may direct.

(c) If an appeal be taken from the judgment of the court before such publication, that fact shall appear.

Subpart E—Imports

§ 1230.40 Required label information.

Containers which are offered for import shall in all cases bear labels or stickers having thereon the information required by section 2(b) (1), (2), and (3) of the Federal Caustic Poison Act and the directions for treatment in the case of personal injury, except such directions need not appear on the label or sticker at the time of shipment by a wholesaler or manufacturer for other than household use.

§ 1230.41 Delivery of containers.

Containers shall not be delivered to the consignee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such containers, together with the duty thereon, and the refusal of the consignee to return such containers for any cause to the custody of the District Director of Customs when demanded, for the purpose of excluding them from the country or for any other purpose, the consignee shall pay an amount equal to the sum named in the bond, and such part of the duty, if any, as may be payable, as liquidated damages for failure to return to the District Director of Customs on demand all containers covered by the bond.

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§ 1230.42 Invoices.

As soon as the importer makes entry, the invoices covering containers and the public stores packages shall be made available, with the least possible delay, for inspection by the representative of the district. When no sample is desired the invoice shall be stamped by the district “No sample desired, Food and Drug Administration, Department of Health and Human Services, per (initials of inspecting officer).”

§ 1230.43 Enforcement.

(a) *Enforcement agency.* The Federal Caustic Poison Act shall be enforced by the Food and Drug Administration, Department of Health and Human Services.

(b) *Enforcement of provisions.* The enforcement of the provisions of the Federal Caustic Poison Act as they relate to imported dangerous caustic or corrosive substances, will, as a general rule, be under the direction of the chief of the local inspection district of the Food and Drug Administration, Department of Health and Human Services, and District Directors of Customs acting as administrative officers in carrying out directions relative to the detention, exportation, and sale, or other disposition of such substances and action under the bond in case of noncompliance with the provisions of the Federal Caustic Poison Act.

(c) *Chief of district as customs officer.* The chief of district shall be deemed a customs officer in enforcing import regulations.

(d) *Nonlaboratory ports.* (1) At the ports of entry where there is no district of the Food and Drug Administration, the District Director of Customs or deputy, on the day when the first notice of expected shipment of containers is received, either by invoice or entry, shall notify the chief of district in whose territory the port is located.

(2) On the day of receipt of such notice the chief of district shall mail to the District Director of Customs appropriate notice, if no sample is desired. This notice serves as an equivalent to stamping the invoices at district ports with the legend “No sample desired,

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Food and Drug Administration, Department of Health and Human Services, per (initials of inspecting officer).”

(3) If samples are desired, the Chief of district shall immediately notify the District Director of Customs.

(4) The District Director of Customs at once shall forward samples, accompanied by description of shipment.

(5) When samples are desired from each shipment of containers, the chief of district shall furnish to District Director of Customs and deputies at ports within the district's territory a list of such containers, indicating the size of sample necessary. Samples should then be sent promptly on arrival of containers without awaiting special request.

(6) In all other particulars the procedure shall be the same at nonlaboratory ports as at laboratory ports, except that the time consumed in delivery of notices by mail shall be allowed for.

§ 1230.44 Samples.

On the same day that samples are requested by the district, the District Director of Customs or appraiser shall notify the importer that samples will be taken, that the containers must be held intact pending a notice of the result of inspection and analysis, and that in case the containers do not comply with the requirements of the Federal Caustic Poison Act, they must be returned to the District Director of Customs for disposition. This notification may be given by the District Director of Customs or appraiser through individual notices to the importer or by suitable bulletin notices posted daily in the customhouse.

§ 1230.45 No violation; release.

As soon as examination of the samples is completed, if no violation of the act is detected, the chief of the district shall send a notice of release to the importer and a copy of this notice to the District Director of Customs for his information.

§ 1230.46 Violation.

(a) If a violation of the Federal Caustic Poison Act is disclosed, the chief of the district shall send to the importer

due notice of the nature of the violation and of the time and place where evidence may be presented, showing that the containers should not be refused admission. At the same time similar notice regarding detention of the containers shall be sent to the District Director of Customs, requesting him to refuse delivery thereof or to require their return to customs custody if by any chance the containers were released without the bond referred to in § 1230.41. The time allowed the importer for representations regarding the shipment may be extended at his request for a reasonable period to permit him to secure such evidence.

(b) If the importer does not reply to the notice of hearing in person or by letter within the time allowed on the notice, a second notice, marked “second and last notice,” shall be sent at once by the chief of the district, advising him that failure to reply will cause definite recommendation to the District Director of Customs that the containers be refused admission and that the containers be exported within 3 months under customs supervision.

§ 1230.47 Rejected containers.

(a) In all cases where the containers are to be refused admission, the chief of the district within 1 day after hearing, or, if the importer does not appear or reply within 3 days after second notice, shall notify the District Director of Customs in duplicate accordingly.

(b) Not later than 1 day after receipt of this notice the District Director of Customs shall sign and transmit to the importer one of the copies, which shall serve as notification to the importer that the containers must be exported under customs supervision within 3 months from such date, as provided by law; the other notice shall be retained as office record and later returned as a report to the chief of the district. In all cases the importer shall return his notice to the District Director of Customs, properly certified as to the information required, as the form provides.

§ 1230.48 Relabeling of containers.

(a) If containers are to be released after relabeling, a notice shall be sent by the chief of district direct to the importer, a carbon copy being sent to the

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District Director of Customs. This notice must state specifically the conditions to be performed, so as to bring the performance thereof under the provisions of the customs bonds on consumption and warehouse entries, these bonds including provisions requiring compliance with all of the requirements of the Federal Caustic Poison Act and all regulations and instructions issued thereunder. The notice will also state the officer to be notified by the importer when the containers are ready for inspection.

(b) The importer must return the notice to the District Director of Customs or chief of district, as designated, with the certificate thereon filled out, stating that he has complied with the prescribed conditions and that the containers are ready for inspection at the place named.

(c) This notice will be delivered to the inspection officer, who, after inspection, will endorse the result thereof on the back of the notice and return the same to the District Director of Customs or to the chief of district, as the case may be.

(d) When the conditions to be complied with are under the supervision of the chief of district, and these conditions have been fully met, he shall release the containers to the importer, sending a copy of the notice of release to the District Director of Customs for his information. If the containers have not been properly relabeled within the period allowed, the chief of district shall immediately give notice in duplicate to the District Director of Customs of the results of inspection. The District Director of Customs shall sign and immediately transmit one copy of the notice to the importer and proceed in the usual manner.

(e) If the containers are detained subject to relabeling to be performed under the supervision of the District Director of Customs, the District Director of Customs, as soon as relabeling is accomplished, will notify the importer that the containers are released.

(f) If the containers have not been properly relabeled within the period allowed, their sale after labeling as required by the act or other disposition

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must be effected by the District Director of Customs.

(g) When the final action has been taken on containers which have been refused admission, sold, or otherwise disposed of as provided for by the act or which have been relabeled under the supervision of the District Director of Customs, he shall send to the chief of district a notice of such final action, giving the date and disposition.

(h) When relabeling is allowed the importer must furnish satisfactory evidence as to the identity of the containers before release is given. The relabeling must be done at a stated place and apart from other containers of a similar nature.

(i) When containers are shipped to another port for relabeling or exportation, they must be shipped under customs carrier's manifest, in the same manner as shipments in bond.

(j) District Directors of Customs will perform the inspection service whenever containers are to be exported, sold, or otherwise disposed of, and in other cases when there is no officer of the district available.

(k) District Directors of Customs and representatives of the district will confer and arrange the apportionment of the inspection service according to local conditions. Officers of the district will, whenever feasible, perform the inspection service in connection with relabeling.

§ 1230.49 Penalties.

(a) In case of failure to comply with the instructions or recommendations of the chief of district as to conditions under which containers may be disposed of, the District Director of Customs shall notify the chief of district in all cases coming to his attention within 3 days after inspection or after the expiration of the 3 months allowed by law if no action is taken.

(b) The chief of district, upon receipt of the above-described notice, and in all cases of failure to meet the conditions imposed in order to comply with the provisions of the Federal Caustic Poison Act coming directly under his supervision, shall transmit to the District Director of Customs such evidence as he may have at hand tending

to indicate the importer's liability and make a recommendation accordingly.

(c) The District Director of Customs, within 3 days of the receipt of this recommendation, whether favorable or otherwise, shall notify the importer that, the legal period of 3 months for exportation or relabeling having expired, action will be taken within 30 days to enforce the terms of the bond.

PART 1240—CONTROL OF COMMUNICABLE DISEASES

Subpart A—General Provisions

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AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

CROSS REFERENCES: For Department of Health and Human Services regulations relating to foreign quarantine, sanitation measures, and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR parts 71 and 72.

SOURCE: 40 FR 5620, Feb. 6, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 1240.3 General definitions.

As used in this part, terms shall have the following meaning:

(a) *Bactericidal treatment*. The application of a method or substance for the destruction of pathogens and other organisms as set forth in § 1240.10.

(b) *Communicable diseases*. Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(c) *Communicable period*. The period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(d) *Contamination*. The presence of a certain amount of undesirable substance or material, which may contain pathogenic microorganisms.

(e) *Conveyance*. Conveyance means any land or air carrier, or any vessel as defined in paragraph (n) of this section.

(f) *Garbage*. (1) The solid animal and vegetable waste, together with the natural moisture content, resulting from the handling, preparation, or consumption of foods in houses, restaurants, hotels, kitchens, and similar establishments, or (2) any other food waste containing pork.

(g) *Incubation period*. The period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(h) *Interstate traffic*. (1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession,

(i) From a point of origin in any State or possession to a point of destination in any other State or possession, or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

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(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(i) *Milk*. Milk is the product defined in § 131.110 of this chapter.

(j) *Milk products*. Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

(k) *Minimum heat treatment*. The causing of all particles in garbage to be heated to a boiling temperature and held at that temperature for a period of not less than 30 minutes.

(l) *Possession*. Any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(m) *Potable water*. Water which meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141 and the Food and Drug Administration's sanitation requirements as set forth in this part and part 1250 of this chapter.

(n) *State*. Any State, the District of Columbia, Puerto Rico and the Virgin Islands.

(o) *Utensil*. Includes any kitchenware, tableware, glassware, cutlery, containers, or equipment with which food or drink comes in contact during storage, preparation, or serving.

(p) *Vessel*. Any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

(q) *Watering point*. The specific place or water boat from which potable water is loaded on a conveyance.

(r) *Molluscan shellfish*. Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 57 FR 57344, Dec. 4, 1992; 60 FR 65201, Dec. 18, 1995]

§ 1240.10 Effective bactericidal treatment.

Whenever, under the provisions of this part, bactericidal treatment is required, it shall be accomplished by one or more of the following methods:

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(a) By immersion of the utensil or equipment for at least 2 minutes in clean hot water at a temperature of at least 170 °F or for one-half minute in boiling water;

(b) By immersion of the utensil or equipment for at least 2 minutes in a lukewarm chlorine bath containing at least 50 ppm of available chlorine if hypochlorites are used or a concentration of equal bactericidal strength if chloramines are used;

(c) By exposure of the utensil or equipment in a steam cabinet at a temperature of at least 170 °F for at least 15 minutes or at a temperature of 200 °F for at least 5 minutes;

(d) By exposure of the utensil or equipment in an oven or hot air cabinet at a temperature of at least 180 °F for at least 20 minutes;

(e) In the case of utensils or equipment so designed or installed as to make immersion or exposure impractical, the equipment may be treated for the prescribed periods of time either at the temperatures or with chlorine solutions as specified above, (1) with live steam from a hose if the steam can be confined, (2) with boiling rinse water, or (3) by spraying or swabbing with chlorine solution;

(f) Any other method determined by the Commissioner of Food and Drugs, upon application of an owner or operator of a conveyance, to be effective to prevent the spread of communicable disease.

[40 FR 5620, Feb. 6, 1975, as amended at 54 FR 24900, June 12, 1989]

Subpart B—Administrative Procedures

§ 1240.20 Issuance and posting of certificates following inspections.

The Commissioner of Food and Drugs may issue certificates based upon inspections provided for in this part and part 1250. Such certificates shall be prominently posted on conveyances.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

§ 1240.30 Measures in the event of inadequate local control.

Whenever the Commissioner of Food and Drugs determines that the meas-

ures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he may take such measures to prevent such spread of the diseases as he deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

§ 1240.45 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

Subpart C [Reserved]

Subpart D—Specific Administrative Decisions Regarding Interstate Shipments

§ 1240.60 Molluscan shellfish.

(a) A person shall not offer for transportation, or transport, in interstate traffic any molluscan shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated, as to render such molluscan shellfish likely to become agents in, and their transportation likely to contribute to the spread of communicable disease from one State or possession to another.

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag,

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bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label, or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

[40 FR 5620, Feb. 6, 1975, as amended at 60 FR 65202, Dec. 18, 1995]

§ 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

(b) Except as provided in paragraphs (c) and (d) of this section, the terms “pasteurization,” “pasteurized,” and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
145 °F (63 °C) ¹	30 minutes.
161 °F (72 °C) ¹	15 seconds.
191 °F (89 °C)	1 second.

¹ If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

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Temperature	Time
194 °F (90 °C)	0.5 second.
201 °F (94 °C)	0.1 second.
204 °F (96 °C)	0.05 second.
212 °F (100 °C)	0.01 second.

(c) Eggnog shall be heated to at least the following temperature and time specification:

Temperature	Time
155 °F (69 °C)	30 minutes.
175 °F (80 °C)	25 seconds.
180 °F (83 °C)	15 seconds.

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

[52 FR 29514, Aug. 10, 1987, as amended at 57 FR 57344, Dec. 4, 1992]

§ 1240.62 Turtles intrastate and interstate requirements.

(a) *Definition.* As used in this section the term “turtles” includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (families Dermachelidae and Chelonidae).

(b) *Sales; general prohibition.* Except as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution.

(c) *Destruction of turtles or turtle eggs; criminal penalties.* (1) Any viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of the Food and Drug Administration in accordance with the following procedures:

(i) Any District Office of the Food and Drug Administration, upon detecting viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial

or public distribution, shall serve upon the person in whose possession such turtles or turtle eggs are found a written demand that such turtles or turtle eggs be destroyed in a humane manner under the supervision of said District Office, within 10 working days from the date of promulgation of the demand. The demand shall recite with particularity the facts which justify the demand. After service of the demand, the person in possession of the turtles or turtle eggs shall not sell, distribute, or otherwise dispose of any of the turtles or turtle eggs except to destroy them under the supervision of the District Office, unless and until the Director of the Center for Veterinary Medicine withdraws the demand for destruction after an appeal pursuant to paragraph (c)(1)(ii) of this section.

(ii) The person on whom the demand for destruction is served may either comply with the demand or, within 10 working days from the date of its promulgation, appeal the demand for destruction to the Director of the Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. The demand for destruction may also be appealed within the same period of 10 working days by any other person having a pecuniary interest in such turtles or turtle eggs. In the event of such an appeal, the Center Director shall provide an opportunity for hearing by written notice to the appellant(s) specifying a time and place for the hearing, to be held within 14 days from the date of the notice but not within less than 7 days unless by agreement with the appellant(s).

(iii) Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The hearing shall be conducted by the Center Director or his designee, and a written summary of the proceedings shall be prepared by the person presiding. Any appellant shall have the right to hear and to question the evidence on which the demand for destruction is based, including the right to cross-examine witnesses, and he may present oral or written evidence in response to the demand.

(iv) If, based on the evidence presented at the hearing, the Center Di-

rector finds that the turtles or turtle eggs were held for sale or offered for any other type of commercial or public distribution in violation of this section, he shall affirm the demand that they be destroyed under the supervision of an officer or employee of the Food and Drug Administration; otherwise, the Center Director shall issue a written notice that the prior demand by the District Office is withdrawn. If the Center Director affirms the demand for destruction he shall order that the destruction be accomplished in a humane manner within 10 working days from the date of the promulgation of his decision. The Center Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Center Director shall constitute final agency action, reviewable in the courts.

(v) If there is no appeal to the Director of the Center for Veterinary Medicine from the demand by the Food and Drug Administration District Office and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, or if the demand is affirmed by the Director of the Center for Veterinary Medicine after an appeal and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, the District Office shall designate an officer or employee to destroy the turtles or turtle eggs. It shall be unlawful to prevent or to attempt to prevent such destruction of turtles or turtle eggs by the officer or employee designated by the District Office. Such destruction will be stayed if so ordered by a court pursuant to an action for review in the courts as provided in paragraph (c)(1)(iv) of this section.

(2) Any person who violates any provision of this section, including but not limited to any person who sells, offers for sale, or offers for any other type of commercial or public distribution viable turtle eggs or live turtles with a carapace length of less than 4 inches, or who refuses to comply with a valid final demand for destruction of turtles or turtle eggs (either an unappealed demand by an FDA District Office or a demand which has been affirmed by the Director of the Center for Veterinary Medicine pursuant to appeal), or who

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fails to comply with the requirement in such a demand that the manner of destruction be humane, shall be subject to a fine of not more than \$1,000 or imprisonment for not more than 1 year, or both, for each violation, in accordance with section 368 of the Public Health Service Act (42 U.S.C. 271).

(d) *Exceptions.* The provisions of this section are not applicable to:

(1) The sale, holding for sale, and distribution of live turtles and viable turtle eggs for bona fide scientific, educational, or exhibitional purposes, other than use as pets.

(2) The sale, holding for sale, and distribution of live turtles and viable turtle eggs not in connection with a business.

(3) The sale, holding for sale, and distribution of live turtles and viable turtle eggs intended for export only, provided that the outside of the shipping package is conspicuously labeled "For Export Only."

(4) Marine turtles excluded from this regulation under the provisions of paragraph (a) of this section and eggs of such turtles.

(e) *Petitions.* The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation. A petition requesting such a regulation, which would amend this regulation, shall be submitted to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[40 FR 22545, May 23, 1975, as amended at 46 FR 8461, Jan. 27, 1981; 48 FR 11431, Mar. 18, 1983; 54 FR 24900, June 12, 1989; 59 FR 14366, Mar. 28, 1994; 66 FR 56035, Nov. 6, 2001; 70 FR 48073, Aug. 18, 2005]

§ 1240.65 Psittacine birds.

(a) The term psittacine birds shall include all birds commonly known as parrots, Amazons, Mexican double heads, African grays, cocatoos, macaws, parakeets, love birds, lorries, lorikeets, and all other birds of the psittacine family.

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(b) No person shall transport, or offer for transportation, in interstate traffic any psittacine bird unless the shipment is accompanied by a permit from the State health department of the State of destination where required by such department.

(c) Whenever the Surgeon General finds that psittacine birds or human beings in any area are infected with psittacosis and there is such danger of transmission of psittacosis from such area as to endanger the public health, he may declare it an area of infection. No person shall thereafter transport, or offer for transportation, in interstate traffic any psittacine bird from such area, except shipments authorized by the Surgeon General for purposes of medical research and accompanied by a permit issued by him, until the Surgeon General finds that there is no longer any danger of transmission of psittacosis from such area. As used in this paragraph, the term "area" includes, but is not limited to, specific premises or buildings.

§ 1240.75 Garbage.

(a) A person shall not transport, receive, or cause to be transported or received, garbage in interstate traffic and feed such garbage to swine unless, prior to the feeding, such garbage has received minimum heat treatment.

(b) A person transporting garbage in interstate traffic shall not make, or agree to make, delivery thereof to any person with knowledge of the intent or customary practice of such person to feed to swine garbage which has not been subjected to minimum heat treatment.

Subpart E—Source and Use of Potable Water

§ 1240.80 General requirements for water for drinking and culinary purposes.

Only potable water shall be provided for drinking and culinary purposes by any operator of a conveyance engaged in interstate traffic, except as provided in §1250.84(b) of this chapter. Such water shall either have been obtained from watering points approved by the Commissioner of Food and Drugs, or, if treated aboard a conveyance, shall

have been subjected to treatment approved by the Commissioner of Food and Drugs.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

§ 1240.83 Approval of watering points.

(a) The Commissioner of Food and Drugs shall approve any watering point if (1) the water supply thereat meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141, and (2) the methods of and facilities for delivery of such water to the conveyance and the sanitary conditions surrounding such delivery prevent the introduction, transmission, or spread of communicable diseases.

(b) The Commissioner of Food and Drugs may base his approval or disapproval of a watering point upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) If a watering point has not been approved, the Commissioner of Food and Drugs may permit its temporary use under such conditions as, in his judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases.

(d) Upon request of the Commissioner of Food and Drugs, operators of conveyances shall provide information as to watering points used by them.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 48 FR 13978, Apr. 1, 1983]

§ 1240.86 Protection of pier water system.

No vessel engaged in interstate traffic shall make a connection between its nonpotable water system and any pier potable water system unless provisions are made to prevent backflow from the vessel to the pier.

§ 1240.90 Approval of treatment aboard conveyances.

(a) The treatment of water aboard conveyances shall be approved by the Commissioner of Food and Drugs if the apparatus used is of such design and is so operated as to be capable of pro-

ducing and in fact does produce, potable water.

(b) The Commissioner of Food and Drugs may base his approval or disapproval of the treatment of water upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) Overboard water treated on vessels shall be from areas relatively free of contamination and pollution.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

§ 1240.95 Sanitation of water boats.

No vessel engaged in interstate traffic shall obtain water for drinking and culinary purposes from any water boat unless the tanks, piping, and other appurtenances used by the water boat in the loading, transportation, and delivery of such drinking and culinary water, have been approved by the Commissioner of Food and Drugs.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

PART 1250—INTERSTATE CONVEYANCE SANITATION

Subpart A—General Provisions

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- 1250.90 Toilets and lavatories.
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- 1250.96 Rodent control.

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

CROSS REFERENCES: For Department of Health and Human Services regulations relating to foreign quarantine and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR parts 71 and 72.

SOURCE: 40 FR 5624, Feb. 6, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 1250.3 Definitions.

As used in this part, terms shall have the following meaning:

(a) *Bactericidal treatment*. The application of a method or substance for the

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destruction of pathogens and other organisms as set forth in § 1240.10 of this chapter.

(b) *Communicable diseases*. Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(c) *Communicable period*. The period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(d) *Contamination*. The presence of a certain amount of undesirable substance or material, which may contain pathogenic microorganisms.

(e) *Conveyance*. Conveyance means any land or air carrier, or any vessel as defined in paragraph (m) of this section.

(f) *Existing vessel*. Any vessel the construction of which was started prior to the effective date of the regulations in this part.

(g) *Garbage*. (1) The solid animal and vegetable waste, together with the natural moisture content, resulting from the handling, preparation, or consumption of foods in houses, restaurants, hotels, kitchens, and similar establishments, or (2) any other food waste containing pork.

(h) *Interstate traffic*. (1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (i) from a point of origin in any State or possession to a point of destination in any other State or possession, or (ii) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(i) *Possession*. Any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(j) *Potable water*. Water which meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141 and the Food and Drug Administration's sanitation regulations as set forth in this part and part 1240 of this chapter.

(k) *State*. Any State, the District of Columbia, Puerto Rico and the Virgin Islands.

(l) *Utensil*. Includes any kitchenware, tableware, glassware, cutlery, containers, or equipment with which food or drink comes in contact during storage, preparation, or serving.

(m) *Vessel*. Any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

(n) *Wash water*. Water suitable for domestic uses other than for drinking and culinary purposes, and medical care purposes excluding hydrotherapy.

(o) *Shellfish*. Any fresh, frozen, or incompletely cooked oysters, clams, or mussels, either shucked or in the shell, and any fresh, frozen, or incompletely cooked edible products thereof.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

Subpart B—Food Service Sanitation on Land and Air Conveyances, and Vessels

§ 1250.20 Applicability.

All conveyances engaged in interstate traffic shall comply with the requirements prescribed in this subpart and § 1240.20 of this chapter.

§ 1250.21 Inspection.

The Commissioner of Food and Drugs may inspect such conveyance to determine compliance with the requirements of this subpart and § 1240.20 of this chapter.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.22 General requirements.

All food and drink served on conveyances shall be clean, wholesome, and free from spoilage, and shall be prepared, stored, handled, and served in accordance with the requirements prescribed in this subpart and § 1240.20 of this chapter.

§ 1250.25 Source identification and inspection of food and drink.

(a) Operators of conveyances shall identify, when requested by the Commissioner of Food and Drugs, the vendors, distributors or dealers from whom they have acquired or are acquiring their food supply, including milk, fluid milk products, ice cream and other frozen desserts, butter, cheese, bottled water, sandwiches and box lunches.

(b) The Commissioner of Food and Drugs may inspect any source of such food supply in order to determine whether the requirements of the regulations in this subpart and in § 1240.20 of this chapter are being met, and may utilize the results of inspections of such sources made by representatives of State health departments or of the health authorities of contiguous foreign nations.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.26 Special food requirements.

Milk, fluid milk products, ice cream and other frozen desserts, butter, cheese, and shellfish served or sold on

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conveyances shall conform to the following requirements:

(a) Milk and fluid milk products, including cream, buttermilk, skim milk, milk beverages, and reconstituted milk, shall be pasteurized and obtained from a source of supply approved by the Commissioner of Food and Drugs. The Commissioner of Food and Drugs shall approve any source of supply at or from which milk or fluid milk products are produced, processed, and distributed so as to prevent the introduction, transmission, or spread of communicable diseases. If a source of supply of milk or fluid milk products has not been approved, the Commissioner of Food and Drugs may permit its temporary use under such conditions as, in his judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases. Containers of milk and fluid milk products shall be plainly labeled to show the contents, the word "pasteurized", and the identity of the plant at which the contents were packaged by name and address, provided that a code may be used in lieu of address.

(b) Ice cream, other frozen desserts, and butter shall be manufactured from milk or milk products that have been pasteurized or subjected to equivalent heat treatment.

(c) Cheese shall be (1) pasteurized or subjected to equivalent heat treatment, (2) made from pasteurized milk products or from milk products which have been subjected to equivalent heat treatment, or (3) cured for not less than 60 days at a temperature not less than 35 °F.

(d) Milk, buttermilk, and milk beverages shall be served in or from the original individual containers in which received from the distributor, or from a bulk container equipped with a dispensing device so designed, constructed, installed, and maintained as to prevent the transmission of communicable diseases.

(e) Shellfish purchased for consumption on any conveyance shall originate from a dealer currently listed by the Public Health Service as holding an unexpired and unrevoked certificate issued by a State authority.

(f) Shucked shellfish shall be purchased in the containers in which they

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are placed at the shucking plant and shall be kept therein until used. The State abbreviation and the certificate number of the packers shall be permanently recorded on the container.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.27 Storage of perishables.

All perishable food or drink shall be kept at or below 50 °F, except when being prepared or kept hot for serving.

§ 1250.28 Source and handling of ice.

Ice coming in contact with food or drink and not manufactured on the conveyance shall be obtained from sources approved by competent health authorities. All ice coming in contact with food or drink shall be stored and handled in such manner as to avoid contamination.

§ 1250.30 Construction, maintenance and use of places where food is prepared, served, or stored.

(a) All kitchens, galleys, pantries, and other places where food is prepared, served, or stored shall be adequately lighted and ventilated: *Provided, however*, That ventilation of cold storage rooms shall not be required. All such places where food is prepared, served, or stored shall be so constructed and maintained as to be clean and free from flies, rodents, and other vermin.

(b) Such places shall not be used for sleeping or living quarters.

(c) Water of satisfactory sanitary quality, under head or pressure, and adequate in amount and temperature, shall be easily accessible to all rooms in which food is prepared and utensils are cleaned.

(d) All plumbing shall be so designed, installed, and maintained as to prevent contamination of the water supply, food, and food utensils.

§ 1250.32 Food-handling operations.

(a) All food-handling operations shall be accomplished so as to minimize the possibility of contaminating food, drink, or utensils.

(b) The hands of all persons shall be kept clean while engaged in handling food, drink, utensils, or equipment.

§ 1250.33 Utensils and equipment.

(a) All utensils and working surfaces used in connection with the preparation, storage, and serving of food or beverages, and the cleaning of food utensils, shall be so constructed as to be easily cleaned and self-draining and shall be maintained in good repair. Adequate facilities shall be provided for the cleaning and bactericidal treatment of all multiuse eating and drinking utensils and equipment used in the preparation of food and beverages. An indicating thermometer, suitably located, shall be provided to permit the determination of the hot water temperature when and where hot water is used as the bactericidal agent.

(b) All multiuse eating and drinking utensils shall be thoroughly cleaned in warm water and subjected to an effective bactericidal treatment after each use. All other utensils that come in contact with food and drink shall be similarly treated immediately following the day's operation. All equipment shall be kept clean.

(c) After bactericidal treatment, utensils shall be stored and handled in such manner as to prevent contamination before reuse.

§ 1250.34 Refrigeration equipment.

Each refrigerator shall be equipped with a thermometer located in the warmest portion thereof. Waste water drains from ice boxes, refrigerating equipment, and refrigerated spaces shall be so installed as to prevent backflow of contaminating liquids.

§ 1250.35 Health of persons handling food.

(a) Any person who is known or suspected to be in a communicable period or a carrier of any communicable disease shall not be permitted to engage in the preparation, handling, or serving of water, other beverages, or food.

(b) Any person known or suspected to be suffering from gastrointestinal disturbance or who has on the exposed portion of the body an open lesion or an infected wound shall not be permitted to engage in the preparation, handling, or serving of food or beverages.

§ 1250.38 Toilet and lavatory facilities for use of food-handling employees.

(a) Toilet and lavatory facilities of suitable design and construction shall be provided for use of food-handling employees. Railroad dining car crew lavatory facilities are regulated under § 1250.45.

(b) Signs directing food-handling employees to wash their hands after each use of toilet facilities shall be posted so as to be readily observable by such employees. Hand washing facilities shall include soap, sanitary towels and hot and cold running water or warm running water in lieu of hot and cold running water.

(c) All toilet rooms shall be maintained in a clean condition.

§ 1250.39 Garbage equipment and disposition.

Watertight, readily cleanable non-absorbent containers with close-fitting covers shall be used to receive and store garbage. Garbage and refuse shall be disposed of as frequently as is necessary and practicable.

Subpart C—Equipment and Operation of Land and Air Conveyances**§ 1250.40 Applicability.**

The sanitary equipment and facilities on land and air conveyances engaged in interstate traffic and the use of such equipment and facilities shall comply with the requirements prescribed in this subpart.

§ 1250.41 Submittal of construction plans.

Plans for the construction or major reconstruction of sanitary equipment or facilities for such conveyances shall be submitted to the Commissioner of Food and Drugs for review of the conformity of such plans with the requirements of this subpart, except that submittal of plans shall not be required for any conveyance under reconstruction if the owner or operator thereof has made arrangements satisfactory to the Commissioner of Food and Drugs for inspections of such conveyances while under

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reconstruction for the purpose of determining conformity with those requirements.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.42 Water systems; constant temperature bottles.

(a) The water system, whether of the pressure or gravity type, shall be complete and closed from the filling ends to the discharge taps, except for protected vent openings. The water system shall be protected against back-flow.

(b) Filling pipes or connections through which water tanks are supplied shall be provided on both sides of all new railway conveyances and on existing conveyances when they undergo heavy repairs. All filling connections shall be easily cleanable and so located and protected as to minimize the hazard of contamination of the water supply.

(c) On all new or reconstructed conveyances, water coolers shall be an integral part of the closed system.

(d) Water filters if used on dining cars and other conveyances will be permitted only if they are so operated and maintained at all times as to prevent contamination of the water.

(e) Constant temperature bottles and other containers used for storing or dispensing potable water shall be kept clean at all times and shall be subjected to effective bactericidal treatment as often as may be necessary to prevent the contamination of water so stored and dispensed.

§ 1250.43 Ice.

Ice shall not be permitted to come in contact with water in coolers or constant temperature bottles.

§ 1250.44 Drinking utensils and toilet articles.

(a) No cup, glass, or other drinking utensil which may be used by more than one person shall be provided on any conveyance unless such cup, glass, or drinking utensil shall have been thoroughly cleaned and subjected to effective bactericidal treatment after each individual use.

(b) Towels, combs, or brushes for common use shall not be provided.

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§ 1250.45 Food handling facilities on railroad conveyances.

(a) Both kitchens and pantries of cars hereafter constructed or reconstructed shall be equipped with double sinks, one of which shall be of sufficient size and depth to permit complete immersion of a basket of dishes during bactericidal treatment; in the pantry a dishwashing machine may be substituted for the double sinks. If chemicals are used for bactericidal treatment, 3-compartment sinks shall be provided.

(b) A sink shall be provided for washing and handling cracked ice used in food or drink and shall be used for no other purpose.

(c) Lavatory facilities for the use of the dining car crew shall be provided on each dining car. Such facilities shall be conveniently located and used for hand and face washing only: *Provided, however,* That where the kitchen and pantry on a dining car hereafter constructed or reconstructed are so partitioned or separated as to impede free passage between them lavatory facilities shall be provided in both the kitchen and the pantry.

(d) Wherever toilet and lavatory facilities required by paragraph (c) of this section are not on the dining car, a lavatory shall be provided on the dining car for the use of employees. The lavatory shall be conveniently located and used only for the purpose for which it is installed.

§ 1250.49 Cleanliness of conveyances.

Conveyances while in transit shall be kept clean and free of flies and mosquitoes. A conveyance which becomes infected with vermin shall be placed out of service until such time as it shall have been effectively treated for the destruction of the vermin.

§ 1250.50 Toilet and lavatory facilities.

Where toilet and lavatory facilities are provided on conveyances they shall be so designed as to permit ready cleaning. On conveyances not equipped with retention facilities, toilet hoppers shall be of such design and so located as to prevent spattering of water filling pipes or hydrants.

§ 1250.51 Railroad conveyances; discharge of wastes.

(a) *New railroad conveyances.* Human wastes, garbage, waste water, or other polluting materials shall not be discharged from any new railroad conveyance except at servicing areas approved by the Commissioner of Food and Drugs. In lieu of retention pending discharge at approved servicing areas, human wastes, garbage, waste water, or other polluting materials that have been suitably treated to prevent the spread of communicable diseases may be discharged from such conveyances, except at stations. For the purposes of this section, "new railroad conveyance" means any such conveyance placed into service for the first time after July 1, 1972, and the terms "waste water or other polluting materials" do not include drainage of drinking water taps or lavatory facilities.

(b) *Nonnew railroad conveyances.* Human wastes, garbage, waste water, or other polluting materials shall not be discharged from any railroad conveyance, other than passenger conveyances for which an extension has been granted pursuant to paragraph (f) of this section, after December 31, 1977, except at servicing areas approved by the Commissioner of Food and Drugs. In lieu of retention pending discharge at approved servicing areas, human wastes, garbage, waste water, or other polluting materials that have been suitably treated to prevent the spread of communicable diseases may be discharged from such conveyances, except at stations. The terms "waste water or other polluting materials" do not include drainage of drinking water taps or lavatory facilities.

(c) *Toilets.* When railroad conveyances, occupied or open to occupancy by travelers, are at a station or servicing area, toilets shall be kept locked unless means are provided to prevent contamination of the area or station.

(d) *Submission of annual report.* Each railroad company shall submit to the Center for Food Safety and Applied Nutrition (HFS-627), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, an annual report of accomplishments made in modifying conveyances to achieve compliance with paragraph (b) of this section.

Annual reports shall be required until a report is submitted showing that 100 percent of the company's conveyances can comply with the requirements of paragraph (b) of this section; annual reports shall be required subsequent to such report if conveyances not capable of complying with the requirements of paragraph (b) of this section are acquired. Every railroad company shall have not less than 10 percent of its nonpassenger conveyances that are in operation capable of complying with the requirements of paragraph (b) of this section by December 31, 1974, not less than 40 percent by December 31, 1975, and not less than 70 percent by December 31, 1976. All conveyances, other than passenger conveyances for which an extension has been granted pursuant to paragraph (f) of this section, in operation after December 31, 1977, shall be capable of complying with paragraph (b) of this section.

(e) *Requirements of annual report.* Annual reports required by paragraph (d) of this section shall be submitted within 60 days of the end of each calendar year. Each report shall contain at least the following information:

- (1) Company name and address.
- (2) Name, title, and address of the company's chief operating official.
- (3) Name, title, address, and telephone number of the person designated by the company to be directly responsible for compliance with this section.
- (4) A statement that all new railroad conveyances placed into service after July 1, 1972 meet the requirements of this section.
- (5) A complete, factual, narrative statement explaining why retrofitting of noncomplying nonnew conveyances is incomplete, if it is incomplete.
- (6) A statement of the percentage of conveyances retrofitted with waste discharge facilities in compliance with this section as of the reporting date and the percentage expected to be completed by December 31st of the following year.
- (7) A tabular report with the following vertical columns: equipment type, e.g., locomotive, caboose, passenger car, and any others having toilets; number of toilets per conveyance;

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number of each equipment type in operation; and number of each to be retrofitted by December 31st of each year until 100 percent compliance with this section is achieved.

(f) *Variances and extensions*—(1) *Variances*. Upon application by a railroad company, the Director, Center for Food Safety and Applied Nutrition, may grant a variance from the compliance schedule prescribed in paragraph (d) of this section for nonpassenger conveyances when the requested variance is required to prevent substantial disruption of the railroad company's operations. Such variance shall not affect the final deadline of compliance established in paragraph (d) of this section.

(2) *Extensions*. Upon application by a railroad company, the Director, Center for Food Safety and Applied Nutrition, may grant an extension of time for compliance with the requirements of paragraph (b) of this section beyond December 31, 1977, for passenger conveyances operated by railroad companies when compliance cannot be achieved without substantial disruption of the railroad company's operations.

(3) *Application for variance or extension*. Application for variances or extensions shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Manager, Interstate Travel Sanitation Sub-Program, HFF-312, 5100 Paint Branch Pkwy., College Park, MD 20740, and shall include the following information:

(i) A detailed description of the proposed deviation from the requirements of paragraphs (b) or (d) of this section.

(ii) A report, current to the date of the request for a variance or extension, containing the information required by paragraph (e) of this section.

(4) *Administration of variances and extensions*. (i) Written notification of the granting or refusal of a variance or extension will be provided to the applying railroad company by the Director, Center for Food Safety and Applied Nutrition. The notification of a granted variance will state the approved deviation from the compliance schedule provided for in paragraph (d) of this section. The notification of a granted

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extension will state the final date for compliance with the provisions of paragraph (b) of this section.

(ii) A public file of requested variances and extensions, their disposition, and information relating to pending actions will be maintained in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(iii) After notice to the railroad company and opportunity for hearing in accordance with part 16 of this chapter, a variance or extension may be withdrawn prior to its scheduled termination if the Director, Center for Food Safety and Applied Nutrition, determines that such withdrawal is necessary to protect the public health.

CROSS REFERENCE: For statutory exemptions for "intercity rail passenger service," see section 306(i) of 45 U.S.C. 546(i).

[40 FR 5624, Feb. 6, 1975, as amended at 40 FR 30110, July 17, 1975; 46 FR 8461, Jan. 27, 1981; 48 FR 11432, Mar. 18, 1983; 54 FR 24900, June 12, 1989; 59 FR 14366, Mar. 28, 1994; 61 FR 14481, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

EFFECTIVE DATE NOTE: For a document staying the effectiveness of §1250.51 (b) and (d), see 42 FR 57122, Nov. 1, 1977.

§ 1250.52 Discharge of wastes on highway conveyances.

There shall be no discharge of excrement, garbage, or waste water from a highway conveyance except at servicing areas approved by the Commissioner of Food and Drugs.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.53 Discharge of wastes on air conveyances.

There shall be no discharge of excrement or garbage from any air conveyance except at servicing areas approved by the Commissioner of Food and Drugs.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

Subpart D—Servicing Areas for Land and Air Conveyances

§ 1250.60 Applicability.

Land and air conveyances engaged in interstate traffic shall use only such servicing areas within the United

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States as have been approved by the Commissioner of Food and Drugs as being in compliance with the requirements prescribed in this subpart.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.61 Inspection and approval.

The Commissioner of Food and Drugs may inspect any such areas to determine whether they shall be approved. He may base his approval or disapproval on investigations made by representatives of State departments of health.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.62 Submittal of construction plans.

Plans for construction or major reconstruction of sanitation facilities at servicing areas shall be submitted to the Commissioner of Food and Drugs for review of the conformity of the proposed facilities with the requirements of this subpart.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.63 General requirements.

Servicing areas shall be provided with all necessary sanitary facilities so operated and maintained as to prevent the spread of communicable diseases.

§ 1250.65 Drainage.

All platforms and other places at which water or food supplies are loaded onto or removed from conveyances shall be adequately drained so as to prevent pooling.

§ 1250.67 Watering equipment.

(a) *General requirements.* All servicing area piping systems, hydrants, taps, faucets, hoses, buckets, and other appurtenances necessary for delivery of drinking and culinary water to a conveyance shall be designed, constructed, maintained and operated in such a manner as to prevent contamination of the water.

(b) *Outlets for nonpotable water.* Outlets for nonpotable water shall be provided with fittings different from those provided for outlets for potable water and each nonpotable water outlet shall

be posted with permanent signs warning that the water is unfit for drinking.

(c) *Ice.* If bulk ice is used for the cooling of drinking water or other beverages, or for food preservation purposes, equipment constructed so as not to become a factor in the transmission of communicable diseases shall be provided for the storage, washing, handling, and delivery to conveyances of such bulk ice, and such equipment shall be used for no other purposes.

§ 1250.70 Employee conveniences.

(a) There shall be adequate toilet, washroom, locker, and other essential sanitary facilities readily accessible for use of employees adjacent to places or areas where land and air conveyances are serviced, maintained, and cleaned. These facilities shall be maintained in a clean and sanitary condition at all times.

(b) In the case of diners not in a train but with a crew on board, adequate toilet facilities shall be available to the crew within a reasonable distance but not exceeding 500 feet of such diners.

(c) Drinking fountains and coolers shall be constructed of impervious, nonoxidizing material, and shall be so designed and constructed as to be easily cleaned. The jet of a drinking fountain shall be slanting and the orifice of the jet shall be protected by a guard in such a manner as to prevent contamination thereof by droppings from the mouth. The orifice of such a jet shall be located a sufficient distance above the rim of the basin to prevent backflow.

§ 1250.75 Disposal of human wastes.

(a) At servicing areas and at stations where land and air conveyances are occupied by passengers the operations shall be so conducted as to avoid contamination of such areas and stations by human wastes.

(b) Toilet wastes shall be disposed of through sanitary sewers or by other methods assuring sanitary disposal of such wastes. All soil cans and removable containers shall be thoroughly cleaned before being returned to use. Equipment for cleaning such containers and for flushing nonremovable containers and waste carts shall be so designed as to prevent backflow into

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the water line, and such equipment shall be used for no purpose connected with the handling of food, water or ice.

(c) All persons who have handled soil cans or other containers which have come in contact with human wastes shall be required to wash their hands thoroughly with soap and warm water and to remove any garments which have become soiled with such wastes before engaging in any work connected with the loading, unloading, transporting or other handling of food, water or ice.

§ 1250.79 Garbage disposal.

(a) Water-tight, readily cleanable, nonabsorbent containers with close-fitting covers shall be used to receive and store garbage.

(b) Can washing and draining facilities shall be provided.

(c) Garbage cans shall be emptied daily and shall be thoroughly washed before being returned for use.

Subpart E—Sanitation Facilities and Conditions on Vessels

§ 1250.80 Applicability.

The sanitation facilities and the sanitary conditions on vessels engaged in interstate traffic shall comply with the requirements prescribed in this subpart, provided that no major structural change will be required on existing vessels.

§ 1250.81 Inspection.

The Commissioner of Food and Drugs may inspect such vessels to determine compliance with the requirements of this subpart.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.82 Potable water systems.

The following conditions must be met by vessel water systems used for the storage and distribution of water which has met the requirements of § 1240.80 of this chapter.

(a) The potable water system, including filling hose and lines, pumps, tanks, and distributing pipes, shall be separate and distinct from other water systems and shall be used for no other purposes.

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(b) All potable water tanks shall be independent of any tanks holding non-potable water or other liquid. All potable water tanks shall be independent of the shell of the ship unless (1) the bottom of the tank is at least 2 feet above the maximum load water line, (2) the seams in the shell are continuously welded, and (3) there are no rivets in that part of the shell which forms a side of a tank. A deck may be used as the top of a tank provided there are no access or inspection openings or rivets therein, and the seams are continuously welded. No toilet or urinal shall be installed immediately above that part of the deck which forms the top of a tank. All potable water tanks shall be located at a sufficient height above the bilge to allow for draining and to prevent submergence in bilge water.

(c) Each potable water tank shall be provided with a means of drainage and, if it is equipped with a manhole, overflow, vent, or a device for measuring depth of water, provision shall be made to prevent entrance into the tank of any contaminating substance. No deck or sanitary drain or pipe carrying any nonpotable water or liquid shall be permitted to pass through the tank.

(d) Tanks and piping shall bear clear marks of identification.

(e) There shall be no backflow or cross connection between potable water systems and any other systems. Pipes and fittings conveying potable water to any fixture, apparatus, or equipment shall be installed in such way that backflow will be prevented. Waste pipes from any part of the potable water system, including treatment devices, discharging to a drain, shall be suitably protected against backflow.

(f) Water systems shall be cleaned, disinfected, and flushed whenever the Commissioner of Food and Drugs shall find such treatment necessary to prevent the introduction, transmission, or spread of communicable diseases.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.83 Storage of water prior to treatment.

The following requirements with respect to the storage of water on vessels prior to treatment must be met in

order to obtain approval of treatment facilities under § 1240.90 of this chapter.

(a) The tank, whether independent or formed by the skin of the ship, deck, tank top, or partitions common with other tanks, shall be free of apparent leakage.

(b) No sanitary drain shall pass through the tank.

(c) The tank shall be adequately protected against both the backflow and discharge into it of bilge or highly contaminated water.

§ 1250.84 Water in galleys and medical care spaces.

(a) Potable water, hot and cold, shall be available in the galley and pantry except that, when potable water storage is inadequate, nonpotable water may be piped to the galley for deck washing and in connection with garbage disposal. Any tap discharging nonpotable water which is installed for deck washing purposes shall not be more than 18 inches above the deck and shall be distinctly marked "For deck washing only".

(b) In the case of existing vessels on which heat treated wash water has been used for the washing of utensils prior to the effective date of the regulations in this part, such water may continue to be so used provided controls are employed to insure the heating of all water to at least 170 °F before discharge from the heater.

(c) Potable water, hot and cold, shall be available in medical care spaces for hand-washing and for medical care purposes excluding hydrotherapy.

§ 1250.85 Drinking fountains and coolers; ice; constant temperature bottles.

(a) Drinking fountains and coolers shall be constructed of impervious, nonoxidizing material, and shall be so designed and constructed as to be easily cleaned. The jet of a drinking fountain shall be slanting and the orifice of the jet shall be protected by a guard in such a manner as to prevent contamination thereof by droppings from the mouth. The orifice of such a jet shall be located a sufficient distance above the rim of the basin to prevent back-flow.

(b) Ice shall not be permitted to come in contact with water in coolers or constant temperature bottles.

(c) Constant temperature bottles and other containers used for storing or dispensing potable water shall be kept clean at all times and shall be subjected to effective bactericidal treatment after each occupancy of the space served and at intervals not exceeding one week.

§ 1250.86 Water for making ice.

Only potable water shall be piped into a freezer for making ice for drinking and culinary purposes.

§ 1250.87 Wash water.

Where systems installed on vessels for wash water, as defined in § 1250.3(n), do not comply with the requirements of a potable water system, prescribed in § 1250.82, they shall be constructed so as to minimize the possibility of the water therein being contaminated. The storage tanks shall comply with the requirements of § 1250.83, and the distribution system shall not be cross connected to a system carrying water of a lower sanitary quality. All faucets shall be labeled "Unfit for drinking".

§ 1250.89 Swimming pools.

(a) Fill and draw swimming pools shall not be installed or used.

(b) Swimming pools of the recirculation type shall be equipped so as to provide complete circulation, replacement, and filtration of the water in the pool every six hours or less. Suitable means of chlorination and, if necessary, other treatment of the water shall be provided to maintain the residual chlorine in the pool water at not less than 0.4 part per million and the pH (a measure of the hydrogen ion concentration) not less than 7.0.

(c) Flowing-through types of salt water pools shall be so operated that complete circulation and replacement of the water in the pool will be effected every 6 hours or less. The water delivery pipe to the pool shall be independent of all other pipes and shall originate at a point where maximum flushing of the pump and pipe line is effected after leaving polluted waters.

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§ 1250.90 Toilets and lavatories.

Toilet and lavatory equipment and spaces shall be maintained in a clean condition.

§ 1250.93 Discharge of wastes.

Vessels operating on fresh water lakes or rivers shall not discharge sewage, or ballast or bilge water, within such areas adjacent to domestic water intakes as are designated by the Commissioner of Food and Drugs.

CROSS REFERENCE: For Environmental Protection Agency's regulations for vessel sanitary discharges as related to authority under the Federal Water Pollution Control Act, as amended (33 U.S.C. 1314 et seq.), see 40 CFR part 140.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.95 Insect control.

Vessels shall be maintained free of infestation by flies, mosquitoes, fleas, lice, and other insects known to be vectors in the transmission of communicable diseases, through the use of screening, insecticides, and other generally accepted methods of insect control.

§ 1250.96 Rodent control.

Vessels shall be maintained free of rodent infestation through the use of traps, poisons, and other generally accepted methods of rodent control.

PARTS 1251–1269 [RESERVED]

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

Subpart A—General Provisions

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AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

SOURCE: 62 FR 40444, July 29, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1270.1 Scope.

(a) The regulations in this part apply to human tissue and to establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices, or other FDA-regulated commodities do not apply to human tissue, except as specified in this part.

(c) Regulations in this chapter do not apply to autologous human tissue.

(d) Regulations in this chapter do not apply to hospitals or other clinical facilities that receive and store human tissue only for transplantation within the same facility.

§ 1270.3 Definitions.

(a) *Act* for the purpose of this part means the Public Health Service Act, section 361 (42 U.S.C. 264).

(b) *Blood component* means any part of a single-donor unit of blood separated by physical or mechanical means.

(c) *Colloid* means a protein or polysaccharide solution that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment such as albumin, dextran, hetastarch; or certain blood components, such as plasma and platelets.

(d) *Contract services* are those functions pertaining to the recovery, screening, testing, processing, storage, or distribution of human tissue that another establishment agrees to perform for a tissue establishment.

(e) *Crystalloid* means a balanced salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume such as saline, Ringer's lactate solution, or 5 percent dextrose in water.

(f) *Distribution* includes any transfer or shipment of human tissue (including importation or exportation), whether or not such transfer or shipment is entirely intrastate and whether or not possession of the tissue is taken.

(g) *Donor* means a human being, living or dead, who is the source of tissue for transplantation.

(h) *Donor medical history interview* means a documented dialogue with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior; such as the donor if living, the next of kin, the nearest available relative, a member of the donor's household, other individual with an affinity relationship, and/or the primary treating physician. The relevant social history includes questions to elicit whether or not the donor met certain descriptions or engaged in certain activities or behaviors considered to place such an individual at increased risk for HIV and hepatitis.

(i) *Establishment* means any facility under one management including all locations, that engages in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation.

(j) *Human tissue*, for the purpose of this part means any tissue derived from a human body and recovered before May 25, 2005, which:

(1) Is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

(5) Excludes semen or other reproductive tissue, human milk, and bone marrow.

(k) *Importer of record* means the person, establishment or their representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

(l) *Legislative consent* means relating to any of the laws of the various States that allow the medical examiner or coroner to procure corneal tissue in the absence of consent of the donor's next-of-kin.

(m) *Person* includes an individual, partnership, corporation, association, or other legal entity.

(n) *Physical assessment* means a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any signs of HIV and hepatitis infection or signs suggestive of any risk factor for such infections.

(o) *Plasma dilution* means a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids.

(p) *Processing* means any activity performed on tissue, other than tissue recovery, including preparation, preservation for storage, and/or removal from storage to assure the quality and/or sterility of human tissue. Processing includes steps to inactivate and remove adventitious agents.

(q) *Quarantine* means the identification of human tissue as not suitable for transplantation, including human tissue that has not yet been characterized as being suitable for transplantation. Quarantine includes the storage of such tissue in an area clearly identified for such use, or other procedures, such as automated designation, for prevention of release of such tissue for transplantation.

(r) *Reconstituted blood* means the extracorporeal resuspension of a blood unit labeled as "Red Blood Cells" by the addition of colloids and/or crystalloids to produce a hematocrit in the normal range.

(s) *Recovery* means the obtaining from a donor of tissue that is intended for use in human transplantation.

(t) *Relevant medical records* means a collection of documents including a donor medical history interview, a physical assessment of the donor, laboratory test results, medical records, existing coroner and autopsy reports, or information obtained from any source or records which may pertain to donor suitability regarding high risk

behaviors, clinical signs and symptoms for HIV and hepatitis, and treatments related to medical conditions suggestive of such risk.

(u) *Responsible person* means a person who is authorized to perform designated functions for which he or she is trained and qualified.

(v) *Storage* means holding tissue.

(w) *Summary of records* means a condensed version of the required testing and screening records that contains the identity of the testing laboratory, the listing and interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of the human tissue for transplantation.

(x) *Vascularized* means containing the original blood vessels which are intended to carry blood after transplantation.

[62 FR 40444, July 29, 1997, as amended at 69 FR 68680, Nov. 24, 2004]

Subpart B—Donor Screening and Testing

§ 1270.21 Determination of donor suitability for human tissue intended for transplantation.

(a) Donor specimens shall be tested for the following communicable viruses, using Food and Drug Administration (FDA) licensed donor screening tests in accordance with manufacturers' instructions:

(1) Human immunodeficiency virus, Type 1 (e.g., FDA licensed screening test for anti-HIV-1);

(2) Human immunodeficiency virus, Type 2 (e.g., FDA licensed screening test for anti-HIV-2);

(3) Hepatitis B (e.g., FDA licensed screening test for HBsAg); and

(4) Hepatitis C (e.g., FDA licensed screening test for anti-HCV).

(b) In the case of a neonate, the mother's specimen is acceptable for testing.

(c) Such infectious disease testing shall be performed by a laboratory certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

(d) Human tissue shall be accompanied by records indicating that the

donor's specimen has been tested and found negative using FDA licensed screening tests for HIV-1, HIV-2, hepatitis B, and hepatitis C. FDA licensed screening tests labeled for cadaveric specimens must be used when available.

(e) Human tissue for transplantation shall be accompanied by a summary of records or copies of the original records of the donor's relevant medical records as defined in §1270.3(t) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, or HIV infection. There shall be a responsible person designated and identified in the original record and summary of records as having made the determination that the human tissue is suitable for transplantation.

(f) Determination by the responsible person that a donor of human tissue intended for transplantation is suitable shall include ascertainment of the donor's identity, and accurately recorded relevant medical records (as defined in §1270.3(t)) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection.

(g) For corneal tissue procured under legislative consent where a donor medical history screening interview has not occurred, a physical assessment of the donor is required and other available information shall be reviewed. The corneal tissue shall be accompanied by the summary of records documenting that the corneal tissue was determined to be suitable for transplantation in the absence of the donor medical history interview. Corneal tissue procured under legislative consent shall be documented as such in the summary of records.

(h) Human tissue shall be determined to be not suitable for transplantation if from:

(1) A donor whose specimen has tested repeatedly reactive on a screening test for HIV, hepatitis B, or hepatitis C;

(2) A donor where blood loss is known or suspected to have occurred and transfusion/infusion of more than 2,000 milliliters (mL) of blood (i.e., whole blood, reconstituted blood, or red blood cells), or colloids within 48 hours; or

more than 2,000 mL of crystalloids within 1 hour; or any combination thereof prior to the collection of a blood specimen from the tissue donor for testing, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results; or

(3) A donor who is 12 years of age or less and has been transfused or infused at all, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results.

Subpart C—Procedures and Records

§ 1270.31 Written procedures.

(a) There shall be written procedures prepared and followed for all significant steps in the infectious disease testing process under § 1270.21 which shall conform to the manufacturers' instructions for use contained in the package inserts for the required tests. These procedures shall be readily available to the personnel in the area where the procedures are performed unless impractical. Any deviation from the written procedures shall be recorded and justified.

(b) There shall be written procedures prepared and followed for all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as provided in § 1270.21. Such procedures shall be readily available to personnel who may perform the procedures. Any deviation from the written procedures shall be recorded and justified.

(c) There shall be written procedures prepared and followed for designating and identifying quarantined tissue.

(d) There shall be written procedures prepared, validated, and followed for prevention of infectious disease contamination or cross-contamination by tissue during processing.

(e) In conformity with this section, any facility may use current standard written procedures such as those in a technical manual prepared by another organization, provided the procedures are consistent with and at least as stringent as the requirements of this part.

§ 1270.33 Records, general requirements.

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease screening and testing of donors of human tissue. All records shall be accurate, indelible, and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.

(b) All human tissue shall be quarantined until the following criteria for donor suitability are satisfied:

(1) All infectious disease testing under § 1270.21 has been completed, reviewed by the responsible person, and found to be negative; and

(2) Donor screening has been completed, reviewed by the responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C.

(c) All human tissue processed or shipped prior to determination of donor suitability must be under quarantine, accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation.

(d) All human tissue determined to be suitable for transplantation must be accompanied by a summary of records, or copies of such original records, documenting that all infectious disease

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testing and screening under § 1270.21 has been completed, reviewed by the responsible person, and found to be negative, and that the tissue has been determined to be suitable for transplantation.

(e) Human tissue shall be quarantined until the tissue is either determined to be suitable for transplantation or appropriate disposition is accomplished.

(f) All persons or establishments that generate records used in determining the suitability of the donor shall retain such records and make them available for authorized inspection or upon request by FDA. The person(s) or establishment(s) making the determination regarding the suitability of the donor shall retain all records, or true copies of such records required under § 1270.21, including all testing and screening records, and shall make them available for authorized inspection or upon request from FDA. Records that can be retrieved from another location by electronic means meet the requirements of this paragraph.

(g) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(h) Records shall be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration, of the tissue, whichever is latest.

[62 FR 40444, July 29, 1997, as amended at 63 FR 16685, Apr. 6, 1998]

§ 1270.35 Specific records.

Records shall be maintained that include, but are not limited to:

(a) Documentation of results and interpretation of all required infectious disease tests;

(b) Information on the identity and relevant medical records of the donor, as required by § 1270.21(e) in English or, if in another language translated to English and accompanied by a statement of authenticity by the translator which specifically identifies the translated document;

(c) Documentation of the receipt and/or distribution of human tissue; and

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(d) Documentation of the destruction or other disposition of human tissue.

Subpart D—Inspection of Tissue Establishments

§ 1270.41 Inspections.

(a) An establishment covered by these regulations in this part, including any location performing contract services, shall permit an authorized inspector of the Food and Drug Administration (FDA) to make at any reasonable time and in a reasonable manner such inspection of the establishment, its facilities, equipment, processes, products, and records as may be necessary to determine compliance with the provisions of this part. Such inspections may be made with or without notice and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) The inspector shall call upon a responsible person of the establishment and may question the personnel of the establishment as the inspector deems necessary.

(d) The inspector may review and copy any records required to be kept pursuant to part 1270.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of human tissue will be handled in accordance with FDA's procedures on disclosure of information as set forth in 21 CFR part 20 of this chapter.

§ 1270.42 Human tissue offered for import.

(a) When human tissue is offered for entry, the importer of record must notify the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which the tissue is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part.

(b) Human tissue offered for import must be quarantined until the human tissue is released by FDA.

§ 1270.43 Retention, recall, and destruction of human tissue.

(a) Upon a finding that human tissue may be in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may:

(1) Serve upon the person who distributed the tissue a written order that the tissue be recalled and/or destroyed, as appropriate, and upon persons in possession of the tissue that the tissue shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the tissue is confirmed; and/or

(2) Take possession of and/or destroy the violative tissue.

(b) The written order will ordinarily provide that the human tissue be recalled and/or destroyed within 5 working days from the date of receipt of the order and will state with particularity the facts that justify the order.

(c) After receipt of an order under this part, the person in possession of the human tissue shall not distribute or dispose of the tissue in any manner except to recall and/or destroy the tissue consistent with the provisions of the order, under the supervision of an authorized official of FDA.

(d) In lieu of paragraphs (b) and (c) of this section, other arrangements for assuring the proper disposition of the tissue may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include providing FDA with records or other written information that adequately assure that the tissue has been recovered, screened, tested, processed, stored, and distributed in conformance with part 1270.

(e) Within 5 working days of receipt of a written order for retention, recall, and/or destruction of tissue (or within 5 working days of the agency's possession of such tissue), the recipient of the written order or prior possessor of such tissue shall request a hearing on the matter in accordance with part 16 of this chapter. The order for destruction will be held in abeyance pending resolution of the hearing request.

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS**Subpart A—General Provisions**

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- 1271.390 Applicability.
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- 1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

AUTHORITY: 42 U.S.C. 216, 243, 263a, 264, 271.

SOURCE: 66 FR 5466, Jan. 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 1271.1 What are the purpose and scope of this part?

(a) *Purpose.* The purpose of this part, in conjunction with §§ 207.20(f), 210.1(c), 210.2, 807.20(d), and 820.1(a) of this chapter, is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-eligibility,

current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope.* (1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, §§ 207.20(f) and 807.20(d) of this chapter require you to register and list your HCT/P's following the procedures in subpart B of this part. Sections 210.1(c), 210.2, 211.1(b), and 820.1(a) of this chapter require you to comply with the donor-eligibility procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

[66 FR 5466, Jan. 19, 2001, as amended at 69 FR 29829, May 25, 2004]

§ 1271.3 How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. "Establishment" includes:

(1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of

human cells, tissues, and cellular and tissue-based products; and

(2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products.

(c) *Homologous use* means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d) *Human cells, tissues, or cellular or tissue-based products (HCT/Ps)* means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/Ps:

(1) Vascularized human organs for transplantation;

(2) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(3) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(4) Minimally manipulated bone marrow for homologous use and not combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);

(5) Ancillary products used in the manufacture of HCT/P;

(6) Cells, tissues, and organs derived from animals other than humans; and

(7) In vitro diagnostic products as defined in §809.3(a) of this chapter.

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled "For use in organ transplantation only."

(e) *Manufacture means*, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.

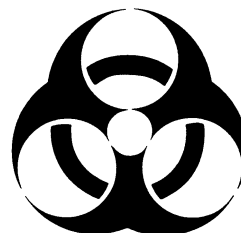
(f) *Minimal manipulation means*:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(g) *Transfer* means the placement of human reproductive cells or tissues into a human recipient.

(h) *Biohazard legend* appears on the label as follows and is used to mark HCT/Ps that present a known or suspected relevant communicable disease risk.



BIOHAZARD

(i) *Blood component* means a product containing a part of human blood separated by physical or mechanical means.

(j) *Colloid* means:

(1) A protein or polysaccharide solution, such as albumin, dextran, or hetastarch, that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment; or

(2) Blood components such as plasma and platelets.

(k) *Crystalloid* means an isotonic salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume, such as saline solution, Ringer's lactate solution, or 5 percent dextrose in water.

(l) *Directed reproductive donor* means a donor of reproductive cells or tissue (including semen, oocytes, and embryos to which the donor contributed

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the spermatozoa or oocyte) to a specific recipient, and who knows and is known by the recipient before donation. The term directed reproductive donor does not include a sexually intimate partner under § 1271.90.

(m) *Donor* means a person, living or dead, who is the source of cells or tissue for an HCT/P.

(n) *Donor medical history interview* means a documented dialog about the donor's medical history and relevant social behavior, including activities, behaviors, and descriptions considered to increase the donor's relevant communicable disease risk:

(1) With the donor, if the donor is living and able to participate in the interview, or

(2) If not, with an individual or individuals able to provide the information sought in the interview (e.g., the donor's next-of-kin, the nearest available relative, a member of the donor's household, an individual with an affinity relationship, and/or the primary treating physician).

(o) *Physical assessment of a cadaveric donor* means a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for signs of a relevant communicable disease and for signs suggestive of any risk factor for a relevant communicable disease.

(p) *Plasma dilution* means a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids.

(q) *Quarantine* means the storage or identification of an HCT/P, to prevent improper release, in a physically separate area clearly identified for such use, or through use of other procedures, such as automated designation.

(r) *Relevant communicable disease agent or disease* means:

(1)(i) For all human cells and tissues, a communicable disease or disease agent listed as follows:

(A) Human immunodeficiency virus, types 1 and 2;

(B) Hepatitis B virus;

(C) Hepatitis C virus;

(D) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease; and

(E) *Treponema pallidum*.

(ii) For viable, leukocyte-rich cells and tissues, a cell-associated disease agent or disease listed as follows:

(A) Human T-lymphotropic virus, type I; and

(B) Human T-lymphotropic virus, type II.

(iii) For reproductive cells or tissues, a disease agent or disease of the genitourinary tract listed as follows:

(A) *Chlamydia trachomatis*; and

(B) *Neisseria gonorrhea*.

(2) A disease agent or disease not listed in paragraph (r)(1) of this section:

(i) For which there may be a risk of transmission by an HCT/P, either to the recipient of the HCT/P or to those people who may handle or otherwise come in contact with it, such as medical personnel, because the disease agent or disease:

(A) Is potentially transmissible by an HCT/P and

(B) Either of the following applies:

(1) The disease agent or disease has sufficient incidence and/or prevalence to affect the potential donor population, or

(2) The disease agent or disease may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection;

(ii) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure; and

(iii) For which appropriate screening measures have been developed and/or an appropriate screening test for donor specimens has been licensed, approved, or cleared for such use by FDA and is available.

(s) *Relevant medical records* means a collection of documents that includes a current donor medical history interview; a current report of the physical assessment of a cadaveric donor or the physical examination of a living donor; and, if available, the following:

(1) Laboratory test results (other than results of testing for relevant communicable disease agents required under this subpart);

(2) Medical records;
(3) Coroner and autopsy reports; and
(4) Records or other information received from any source pertaining to risk factors for relevant communicable disease (e.g., social behavior, clinical signs and symptoms of relevant communicable disease, and treatments related to medical conditions suggestive of risk for relevant communicable disease).

(t) *Responsible person* means a person who is authorized to perform designated functions for which he or she is trained and qualified.

(u) *Urgent medical need* means that no comparable HCT/P is available and the recipient is likely to suffer death or serious morbidity without the HCT/P.

(v) *Act* means the Federal Food, Drug, and Cosmetic Act.

(w) *PHS Act* means the Public Health Service Act.

(x) *FDA* means the Food and Drug Administration.

(y) *Adverse reaction* means a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the HCT/P caused the response.

(z) *Available for distribution* means that the HCT/P has been determined to meet all release criteria.

(aa) *Complaint* means any written, oral, or electronic communication about a distributed HCT/P that alleges:

(1) That an HCT/P has transmitted or may have transmitted a communicable disease to the recipient of the HCT/P; or

(2) Any other problem with an HCT/P relating to the potential for transmission of communicable disease, such as the failure to comply with current good tissue practice.

(bb) *Distribution* means any conveyance or shipment (including importation and exportation) of an HCT/P that has been determined to meet all release criteria, whether or not such conveyance or shipment is entirely intrastate. If an entity does not take physical possession of an HCT/P, the entity is not considered a distributor.

(cc) *Establish and maintain* means define, document (in writing or electronically), and implement; then follow, review, and, as needed, revise on an ongoing basis.

(dd) *HCT/P deviation* means an event:

(1) That represents a deviation from applicable regulations in this part or from applicable standards or established specifications that relate to the prevention of communicable disease transmission or HCT/P contamination; or

(2) That is an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination.

(ee) *Importer of record* means the person, establishment, or its representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

(ff) *Processing* means any activity performed on an HCT/P, other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution, such as testing for microorganisms, preparation, sterilization, steps to inactivate or remove adventitious agents, preservation for storage, and removal from storage.

(gg) *Quality audit* means a documented, independent inspection and review of an establishment's activities related to core CGTP requirements. The purpose of a quality audit is to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

(hh) *Quality program* means an organization's comprehensive system for manufacturing and tracking HCT/Ps in accordance with this part. A quality program is designed to prevent, detect, and correct deficiencies that may lead to circumstances that increase the risk of introduction, transmission, or spread of communicable diseases.

(ii) *Recovery* means obtaining from a human donor cells or tissues that are intended for use in human implantation, transplantation, infusion, or transfer.

(jj) *Storage* means holding HCT/Ps for future processing and/or distribution.

(kk) *Validation* means confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. Validation of a process, or *process validation*, means establishing by objective evidence that a process consistently

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produces a result or HCT/P meeting its predetermined specifications.

(11) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

[66 FR 5466, Jan. 19, 2001, as amended at 68 FR 3826, Jan. 27, 2004; 69 FR 29829, May 25, 2004; 69 FR 68680, Nov. 24, 2004]

§ 1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

(4) Either:

(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

(a) Is for autologous use;

(b) Is for allogeneic use in a first-degree or second-degree blood relative; or

(c) Is for reproductive use.

(b) If you are a domestic or foreign establishment that manufactures an HCT/P described in paragraph (a) of this section:

(1) You must register with FDA;

(2) You must submit to FDA a list of each HCT/P manufactured; and

(3) You must comply with the other requirements contained in this part.

[66 FR 5466, Jan. 19, 2001, as amended at 69 FR 68681, Nov. 24, 2004]

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§ 1271.15 Are there any exceptions from the requirements of this part?

(a) You are not required to comply with the requirements of this part if you are an establishment that uses HCT/P's solely for nonclinical scientific or educational purposes.

(b) You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure.

(c) You are not required to comply with the requirements of this part if you are a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier.

(d) You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within your facility.

(e) You are not required to comply with the requirements of this part if you are an establishment that only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

§ 1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions in § 1271.15, what regulations apply?

If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product under the act and/or section 351 of the PHS Act, and applicable regulations in title 21, chapter I.

Applicable regulations include, but are not limited to, §§ 207.20(f), 210.1(c), 210.2, 211.1(b), 807.20(d), and 820.1(a) of this chapter, which require you to follow the procedures in subparts B, C, and D of this part.

Subpart B—Procedures for Registration and Listing

§ 1271.21 When do I register, submit an HCT/P list, and submit updates?

(a) You must register and submit a list of every HCT/P that your establishment manufactures within 5 days after beginning operations or within 30 days of the effective date of this regulation, whichever is later.

(b) You must update your establishment registration annually in December, except as required by § 1271.26. You may accomplish your annual registration in conjunction with updating your HCT/P list under paragraph (c) of this section.

(c)(i) If no change described in § 1271.25(c) has occurred since you previously submitted an HCT/P list, you are not required to update your listing.

(ii) If a change described in § 1271.25(c) has occurred, you must update your HCT/P listing with the new information:

(a) At the time of the change, or

(b) Each June or December, whichever month occurs first after the change.

[69 FR 68681, Nov. 24, 2004]

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

- (1) Establishment registration,
- (2) HCT/P listings, and
- (3) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(1) By writing to the Center for Biologics Evaluation and Research (HFM-775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator;

(2) By contacting any Food and Drug Administration district office;

(3) By calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800; or

(4) By connecting to <http://www.fda.gov/opacom/morechoices/fdaforms/cber.html> on the Internet.

(c)(1) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM-775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator; or

(2) You may submit Form FDA 3356 electronically through a secure web server at <http://www.fda.gov/cber/tissue/tisreg.htm>.

[69 FR 68681, Nov. 24, 2004]

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration Form FDA 3356 must include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A dated signature by the reporting official affirming that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

(b) Your HCT/P listing must include all HCT/P's (including the established name and the proprietary name) that you recover, process, store, label, package, distribute, or for which you perform donor screening or testing. You must also state whether each HCT/P meets the criteria set out in § 1271.10.

(c) Your HCT/P listing update must include:

(1) A list of each HCT/P that you have begun recovering, processing, storing, labeling, packaging, distributing, or for which you have begun donor screening or testing, that has not been included in any list previously submitted. You must provide all of the information required by § 1271.25(b) for each new HCT/P.

(2) A list of each HCT/P formerly listed in accordance with § 1271.21(a) for which you have discontinued recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including for each HCT/P so

listed, the identity by established name and proprietary name, and the date of discontinuance. We request but do not require that you include the reason for discontinuance with this information.

(3) A list of each HCT/P for which a notice of discontinuance was submitted under paragraph (c)(2) of this section and for which you have resumed recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including the identity by established name and proprietary name, the date of resumption, and any other information required by § 1271.25(b) not previously submitted.

(4) Any material change in any information previously submitted. Material changes include any change in information submitted on Form FDA 3356, such as whether the HCT/P meets the criteria set out in § 1271.10.

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, you must submit an amendment to registration within 5 days of the change.

§ 1271.27 Will FDA assign me a registration number?

(a) FDA will assign each location a permanent registration number.

(b) FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) A copy of the Form FDA 3356 filed by each establishment will be available for public inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for

firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all HCT/P's;
- (2) A list of all HCT/P's manufactured by each establishment;
- (3) A list of all HCT/P's discontinued; and
- (4) All data or information that has already become a matter of public record.

(b) You should direct your requests for information regarding HCT/P establishment registrations and HCT/P listings to the Office of Communication, Training and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

Subpart C—Donor Eligibility

SOURCE: 69 FR 29830, May 25, 2004, unless otherwise noted.

§ 1271.45 What requirements does this subpart contain?

(a) *General.* This subpart sets out requirements for determining donor eligibility, including donor screening and testing. The requirements contained in this subpart are a component of current good tissue practice (CGTP) requirements. Other CGTP requirements are set out in subpart D of this part.

(b) *Donor-eligibility determination required.* A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under § 1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor.

(c) *Prohibition on use.* An HCT/P must not be implanted, transplanted, infused, or transferred until the donor

has been determined to be eligible, except as provided under §§ 1271.60(d), 1271.65(b), and 1271.90 of this subpart.

(d) *Applicability of requirements.* If you are an establishment that performs any function described in this subpart, you must comply with the requirements contained in this subpart that are applicable to that function.

[69 FR 29830, May 25, 2004, as amended at 69 FR 68681, Nov. 24, 2004]

§ 1271.47 What procedures must I establish and maintain?

(a) *General.* You must establish and maintain procedures for all steps that you perform in testing, screening, determining donor eligibility, and complying with all other requirements of this subpart. Establish and maintain means define, document (in writing or electronically), and implement; then follow, review, and as needed, revise on an ongoing basis. You must design these procedures to ensure compliance with the requirements of this subpart.

(b) *Review and approval.* Before implementation, a responsible person must review and approve all procedures.

(c) *Availability.* Procedures must be readily available to the personnel in the area where the operations to which they relate are performed, or in a nearby area if such availability is impractical.

(d) *Departures from procedures.* You must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence. You must not make available for distribution any HCT/P from a donor whose eligibility is determined under such a departure unless a responsible person has determined that the departure does not increase the risks of communicable disease transmission through the use of the HCT/P.

(e) *Standard procedures.* You may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided that you have verified that the procedures are consistent with and at least as stringent as the requirements of this part and appropriate for your operations.

§ 1271.50 How do I determine whether a donor is eligible?

(a) *Determination based on screening and testing.* If you are the establishment responsible for making the donor-eligibility determination, you must determine whether a donor is eligible based upon the results of donor screening in accordance with § 1271.75 and donor testing in accordance with §§ 1271.80 and 1271.85. A responsible person, as defined in § 1271.3(t), must determine and document the eligibility of a cell or tissue donor.

(b) *Eligible donor.* A donor is eligible under these provisions only if:

(1) Donor screening in accordance with § 1271.75 indicates that the donor:

(i) Is free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases; and

(ii) Is free from communicable disease risks associated with xenotransplantation; and

(2) The results of donor testing for relevant communicable disease agents in accordance with §§ 1271.80 and 1271.85 are negative or nonreactive, except as provided in § 1271.80(d)(1).

§ 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I retain?

(a) *Accompanying records.* Once a donor-eligibility determination has been made, the following must accompany the HCT/P at all times:

(1) A distinct identification code affixed to the HCT/P container, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P and, except in the case of autologous donations, directed reproductive donations, or donations made by first-degree or second-degree blood relatives, does not include an individual's name, social security number, or medical record number;

(2) A statement whether, based on the results of screening and testing, the donor has been determined to be eligible or ineligible; and

(3) A summary of the records used to make the donor-eligibility determination.

(b) *Summary of records.* The summary of records required by paragraph (a)(3)

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of this section must contain the following information:

(1) A statement that the communicable disease testing was performed by a laboratory:

(i) Certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493; or

(ii) That has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions;

(2) A listing and interpretation of the results of all communicable disease tests performed;

(3) The name and address of the establishment that made the donor-eligibility determination; and

(4) In the case of an HCT/P from a donor who is ineligible based on screening and released under paragraph (b) of § 1271.65, a statement noting the reason(s) for the determination of ineligibility.

(c) *Deletion of personal information.* The accompanying records required by this section must not contain the donor's name or other personal information that might identify the donor.

(d) *Record retention requirements.* (1) You must maintain documentation of:

(i) Results and interpretation of all testing for relevant communicable disease agents in compliance with §§ 1271.80 and 1271.85, as well as the name and address of the testing laboratory or laboratories;

(ii) Results and interpretation of all donor screening for communicable diseases in compliance with § 1271.75; and

(iii) The donor-eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

(2) All records must be accurate, indelible, and legible. Information on the identity and relevant medical records of the donor, as defined in § 1271.3(s), must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

(3) You must retain required records and make them available for authorized inspection by or upon request from

FDA. Records that can be readily retrieved from another location by electronic means are considered “retained.”

(4) You must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest.

[69 FR 29830, May 25, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?

(a) *Quarantine.* You must keep an HCT/P in quarantine, as defined in § 1271.3(q), until completion of the donor-eligibility determination required by § 1271.50. You must quarantine semen from anonymous donors until the retesting required under § 1271.85(d) is complete.

(b) *Identification of HCT/Ps in quarantine.* You must clearly identify as quarantined an HCT/P that is in quarantine pending completion of a donor-eligibility determination. The quarantined HCT/P must be easily distinguishable from HCT/Ps that are available for release and distribution.

(c) *Shipping of HCT/Ps in quarantine.* If you ship an HCT/P before completion of the donor-eligibility determination, you must keep it in quarantine during shipment. The HCT/P must be accompanied by records:

(1) Identifying the donor (e.g., by a distinct identification code affixed to the HCT/P container);

(2) Stating that the donor-eligibility determination has not been completed; and

(3) Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except under the terms of paragraph (d) of this section.

(d) *Use in cases of urgent medical need.*

(1) This subpart C does not prohibit the implantation, transplantation, infusion, or transfer of an HCT/P from a donor for whom the donor-eligibility determination is not complete if there

is a documented urgent medical need for the HCT/P, as defined in § 1271.3(u).

(2) If you make an HCT/P available for use under the provisions of paragraph (d)(1) of this section, you must prominently label it “NOT EVALUATED FOR INFECTIOUS SUBSTANCES,” and “WARNING: Advise patient of communicable disease risks.” The following information must accompany the HCT/P:

(i) The results of any donor screening required under § 1271.75 that has been completed;

(ii) The results of any testing required under § 1271.80 or 1271.85 that has been completed; and

(iii) A list of any screening or testing required under § 1271.75, 1271.80 or 1271.85 that has not yet been completed.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (d)(1) of this section, you must document that you notified the physician using the HCT/P that the testing and screening were not complete.

(4) In the case of an HCT/P used for an urgent medical need under the provisions of paragraph (d)(1) of this section, you must complete the donor-eligibility determination during or after the use of the HCT/P, and you must inform the physician of the results of the determination.

§ 1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?

(a) *Storage.* If you are the establishment that stores the HCT/P, you must store or identify HCT/Ps from donors who have been determined to be ineligible in a physically separate area clearly identified for such use, or follow other procedures, such as automated designation, that are adequate to prevent improper release until destruction or other disposition of the HCT/P in accordance with paragraph (b) or (c) of this section.

(b) *Limited uses of HCT/P from ineligible donor.* (1) An HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, is not prohibited by subpart C of this part from use

for implantation, transplantation, infusion, or transfer under the following circumstances:

(i) The HCT/P is for allogeneic use in a first-degree or second-degree blood relative;

(ii) The HCT/P consists of reproductive cells or tissue from a directed reproductive donor, as defined in § 1271.3(l); or

(iii) There is a documented urgent medical need as defined in § 1271.3(u).

(2) You must prominently label an HCT/P made available for use under the provisions of paragraph (b)(1) of this section with the Biohazard legend shown in § 1271.3(h) with the statement “WARNING: Advise patient of communicable disease risks,” and, in the case of reactive test results, “WARNING: Reactive test results for (name of disease agent or disease).” The HCT/P must be accompanied by the records required under § 1271.55.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (b)(1) of this section, you must document that you notified the physician using the HCT/P of the results of testing and screening.

(c) *Nonclinical use.* You may make available for nonclinical purposes an HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, provided that it is labeled:

(1) “For Nonclinical Use Only” and

(2) With the Biohazard legend shown in § 1271.3(h).

§ 1271.75 How do I screen a donor?

(a) *All donors.* Except as provided under § 1271.90, if you are the establishment that performs donor screening, you must screen a donor of cells or tissue by reviewing the donor’s relevant medical records for:

(1) Risk factors for, and clinical evidence of, relevant communicable disease agents and diseases, including:

(i) Human immunodeficiency virus;

(ii) Hepatitis B virus;

(iii) Hepatitis C virus;

(iv) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease;

(v) *Treponema pallidum*; and

(2) Communicable disease risks associated with xenotransplantation.

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(b) *Donors of viable, leukocyte-rich cells or tissue.* In addition to the relevant communicable disease agents and diseases for which screening is required under paragraph (a) of this section, and except as provided under § 1271.90, you must screen the donor of viable, leukocyte-rich cells or tissue by reviewing the donor's relevant medical records for risk factors for and clinical evidence of relevant cell-associated communicable disease agents and diseases, including Human T-lymphotropic virus.

(c) *Donors of reproductive cells or tissue.* In addition to the relevant communicable disease agents and diseases for which screening is required under paragraphs (a) and (b) of this section, as applicable, and except as provided under § 1271.90, you must screen the donor of reproductive cells or tissue by reviewing the donor's relevant medical records for risk factors for and clinical evidence of infection due to relevant communicable diseases of the genitourinary tract. Such screening must include screening for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section. However, if the reproductive cells or tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract, then screening for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section is not required. Communicable disease agents of the genitourinary tract for which you must screen include:

- (1) *Chlamydia trachomatis*; and
- (2) *Neisseria gonorrhea*.

(d) *Ineligible donors.* You must determine ineligible a donor who is identified as having either of the following:

(1) A risk factor for or clinical evidence of any of the relevant communicable disease agents or diseases for which screening is required under paragraphs (a)(1), (b), or (c) of this section; or

(2) Any communicable disease risk associated with xenotransplantation.

(e) *Abbreviated procedure for repeat donors.* If you have performed a complete donor screening procedure on a living donor within the previous 6 months,

you may use an abbreviated donor screening procedure on repeat donations. The abbreviated procedure must determine and document any changes in the donor's medical history since the previous donation that would make the donor ineligible, including relevant social behavior.

[66 FR 5466, Jan. 19, 2001, as amended at 71 FR 14798, Mar. 24, 2006]

§ 1271.80 What are the general requirements for donor testing?

(a) *Testing for relevant communicable diseases is required.* To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, if you are the establishment that performs donor testing, you must test a donor specimen for evidence of infection due to communicable disease agents in accordance with paragraph (c) of this section. You must test for those communicable disease agents specified in § 1271.85. In the case of a donor 1 month of age or younger, you must test a specimen from the birth mother instead of a specimen from the donor.

(b) *Timing of specimen collection.* You must collect the donor specimen for testing at the time of recovery of cells or tissue from the donor; or up to 7 days before or after recovery, except:

(1) For donors of peripheral blood stem/progenitor cells, bone marrow (if not excepted under § 1271.3(d)(4)), or oocytes, you may collect the donor specimen for testing up to 30 days before recovery; or

(2) In the case of a repeat semen donor from whom a specimen has already been collected and tested, and for whom retesting is required under § 1271.85(d), you are not required to collect a donor specimen at the time of each donation.

(c) *Tests.* You must test using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases; however, until such time as appropriate FDA-licensed, approved, or cleared donor screening tests for *Chlamydia trachomatis* and for

Neisseria gonorrhea are available, you must use FDA-licensed, approved, or cleared tests labeled for the detection of those organisms in an asymptomatic, low-prevalence population. You must use a test specifically labeled for cadaveric specimens instead of a more generally labeled test when applicable and when available. Required testing under this section must be performed by a laboratory that either is certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

(d) *Ineligible donors.* You must determine the following donors to be ineligible:

(1) A donor whose specimen tests reactive on a screening test for a communicable disease agent in accordance with § 1271.85, except for a donor whose specimen tests reactive on a non-treponemal screening test for syphilis and negative on a specific treponemal confirmatory test;

(2)(i) A donor in whom plasma dilution sufficient to affect the results of communicable disease testing is suspected, unless:

(A) You test a specimen taken from the donor before transfusion or infusion and up to 7 days before recovery of cells or tissue; or

(B) You use an appropriate algorithm designed to evaluate volumes administered in the 48 hours before specimen collection, and the algorithm shows that plasma dilution sufficient to affect the results of communicable disease testing has not occurred.

(ii) Clinical situations in which you must suspect plasma dilution sufficient to affect the results of communicable disease testing include but are not limited to the following:

(A) Blood loss is known or suspected in a donor over 12 years of age, and the donor has received a transfusion or infusion of any of the following, alone or in combination:

(1) More than 2,000 milliliters (mL) of blood (e.g., whole blood, red blood cells) or colloids within 48 hours before

death or specimen collection, whichever occurred earlier, or

(2) More than 2,000 mL of crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

(B) Regardless of the presence or absence of blood loss, the donor is 12 years of age or younger and has received a transfusion or infusion of any amount of any of the following, alone or in combination:

(1) Blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(2) Crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

[69 FR 29830, May 25, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 1271.85 What donor testing is required for different types of cells and tissues?

(a) *All donors.* To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, you must test a specimen from the donor of cells or tissue, whether viable or nonviable, for evidence of infection due to relevant communicable disease agents, including:

(1) Human immunodeficiency virus, type 1;

(2) Human immunodeficiency virus, type 2;

(3) Hepatitis B virus;

(4) Hepatitis C virus; and

(5) *Treponema pallidum*.

(b) *Donors of viable, leukocyte-rich cells or tissue.* In addition to the relevant communicable disease agents for which testing is required under paragraph (a) of this section, and except as provided under § 1271.90,

(1) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue to adequately and appropriately reduce the risk of transmission of relevant cell-associated communicable diseases, including:

(i) Human T-lymphotropic virus, type I; and

(ii) Human T-lymphotropic virus, type II.

(2) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue for evidence of infection

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due to cytomegalovirus (CMV), to adequately and appropriately reduce the risk of transmission. You must establish and maintain a standard operating procedure governing the release of an HCT/P from a donor whose specimen tests reactive for CMV.

(c) *Donors of reproductive cells or tissue.* In addition to the communicable disease agents for which testing is required under paragraphs (a) and (b) of this section, as applicable, and except as provided under § 1271.90, you must test a specimen from the donor of reproductive cells or tissue to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents of the genitourinary tract. Such testing must include testing for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section. However, if the reproductive cells or tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract, then testing for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section is not required. Communicable disease agents of the genitourinary tract for which you must test include:

- (1) *Chlamydia trachomatis*; and
- (2) *Neisseria gonorrhea*.

(d) *Retesting anonymous semen donors.* Except as provided under § 1271.90 and except for directed reproductive donors as defined in § 1271.3(l), at least 6 months after the date of donation of semen from anonymous donors, you must collect a new specimen from the donor and test it for evidence of infection due to the communicable disease agents for which testing is required under paragraphs (a), (b), and (c) of this section.

(e) *Dura mater.* For donors of dura mater, you must perform an adequate assessment designed to detect evidence of transmissible spongiform encephalopathy.

§ 1271.90 Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?

(a) *Donor-eligibility determination not required.* You are not required to make

a donor-eligibility determination under § 1271.50 or to perform donor screening or testing under §§ 1271.75, 1271.80 and 1271.85 for:

(1) Cells and tissues for autologous use; or

(2) Reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use; or

(3) Cryopreserved cells or tissue for reproductive use, other than embryos, originally exempt under paragraphs (a)(1) or (a)(2) of this section at the time of donation, that are subsequently intended for directed donation, provided that

(i) Additional donations are unavailable, for example, due to the infertility or health of a donor of the cryopreserved reproductive cells or tissue; and

(ii) Appropriate measures are taken to screen and test the donor(s) before transfer to the recipient.

(4) A cryopreserved embryo, originally exempt under paragraph (a)(2) of this section at the time of cryopreservation, that is subsequently intended for directed or anonymous donation. When possible, appropriate measures should be taken to screen and test the semen and oocyte donors before transfer of the embryo to the recipient.

(b) *Required labeling.* As applicable, you must prominently label an HCT/P described in paragraph (a) of this section as follows:

(1) “FOR AUTOLOGOUS USE ONLY,” if it is stored for autologous use.

(2) “NOT EVALUATED FOR INFECTIOUS SUBSTANCES,” unless you have performed all otherwise applicable screening and testing under §§ 1271.75, 1271.80, and 1271.85. This paragraph does not apply to reproductive cells or tissue labeled in accordance with paragraph (b)(6) of this section.

(3) Unless the HCT/P is for autologous use only, “WARNING: Advise recipient of communicable disease risks,”

(i) When the donor-eligibility determination under § 1271.50(a) is not performed or is not completed; or

(ii) If the results of any screening or testing performed indicate:

(A) The presence of relevant communicable disease agents and/or

(B) Risk factors for or clinical evidence of relevant communicable disease agents or diseases.

(4) With the Biohazard legend shown in §1271.3(h), if the results of any screening or testing performed indicate:

(i) The presence of relevant communicable disease agents and/or

(ii) Risk factors for or clinical evidence of relevant communicable disease agents or diseases.

(5) "WARNING: Reactive test results for (name of disease agent or disease)," in the case of reactive test results.

(6) "Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive cells or tissue, but have been performed subsequently," for paragraphs (a)(3) or (a)(4) of this section.

[69 FR 29830, May 25, 2004, as amended at 70 FR 29952, May 25, 2005]

Subpart D—Current Good Tissue Practice

SOURCE: 69 FR 68681, Nov. 24, 2004, unless otherwise noted.

§ 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.

You must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

§ 1271.150 Current good tissue practice requirements.

(a) *General.* This subpart D and subpart C of this part set forth current good tissue practice (CGTP) requirements. You must follow CGTP requirements to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (e.g., by ensuring that the HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing). Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria,

fungi, parasites, and transmissible spongiform encephalopathy agents. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP provisions specifically governing determinations of donor eligibility, including donor screening and testing, are set out separately in subpart C of this part.

(b) *Core CGTP requirements.* The following are core CGTP requirements:

(1) Requirements relating to facilities in §1271.190(a) and (b);

(2) Requirements relating to environmental control in §1271.195(a);

(3) Requirements relating to equipment in §1271.200(a);

(4) Requirements relating to supplies and reagents in §1271.210(a) and (b);

(5) Requirements relating to recovery in §1271.215;

(6) Requirements relating to processing and process controls in §1271.220;

(7) Requirements relating to labeling controls in §1271.250(a) and (b);

(8) Requirements relating to storage in §1271.260 (a) through (d);

(9) Requirements relating to receipt, predistribution shipment, and distribution of an HCT/P in §1271.265(a) through (d); and

(10) Requirements relating to donor eligibility determinations, donor screening, and donor testing in §§1271.50, 1271.75, 1271.80, and 1271.85.

(c) *Compliance with applicable requirements*—(1) *Manufacturing arrangements* (i) If you are an establishment that engages in only some operations subject to the regulations in this subpart and subpart C of this part, and not others, then you need only comply with those requirements applicable to the operations that you perform.

(ii) If you engage another establishment (e.g., a laboratory to perform communicable disease testing, or an irradiation facility to perform terminal sterilization), under a contract, agreement, or other arrangement, to perform any step in manufacture for you, that establishment is responsible for complying with requirements applicable to that manufacturing step.

(iii) Before entering into a contract, agreement, or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies with applicable CGTP requirements. If, during the course of this contract, agreement, or other arrangement, you become aware of information suggesting that the establishment may no longer be in compliance with such requirements, you must take reasonable steps to ensure the establishment complies with those requirements. If you determine that the establishment is not in compliance with those requirements, you must terminate your contract, agreement, or other arrangement with the establishment.

(2) If you are the establishment that determines that an HCT/P meets all release criteria and makes the HCT/P available for distribution, whether or not you are the actual distributor, you are responsible for reviewing manufacturing and tracking records to determine that the HCT/P has been manufactured and tracked in compliance with the requirements of this subpart and subpart C of this part and any other applicable requirements.

(3) With the exception of §§ 1271.150(c) and 1271.155 of this subpart, the regulations in this subpart are not being implemented for reproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, or for the establishments that manufacture them.

(d) *Compliance with parts 210, 211, and 820 of this chapter.* With respect to HCT/Ps that are drugs (subject to review under an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or under a biological product license application under section 351 of the Public Health Service Act) or that are devices (subject to pre-market review or notification under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act), the procedures contained in this subpart and in subpart C of this part and the current good manufacturing practice regulations in parts 210 and 211 of this chapter and the quality system regulations in part 820

of this chapter supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event that a regulation in part 1271 of this chapter is in conflict with a requirement in parts 210, 211, or 820 of this chapter, the regulations more specifically applicable to the product in question will supersede the more general.

(e) *Where appropriate.* When a requirement is qualified by “where appropriate,” it is deemed to be “appropriate” unless you can document justification otherwise. A requirement is “appropriate” if nonimplementation of the requirement could reasonably be expected to result in the HCT/P not meeting its specified requirements related to prevention of introduction, transmission, or spread of communicable diseases, or in your inability to carry out any necessary corrective action.

§ 1271.155 Exemptions and alternatives.

(a) *General.* You may request an exemption from or alternative to any requirement in subpart C or D of this part.

(b) *Request for exemption or alternative.* Submit your request under this section to the Director of the appropriate Center (the Director), e.g., the Center for Biologics Evaluation and Research or the Center for Devices and Radiological Health. The request must be accompanied by supporting documentation, including all relevant valid scientific data, and must contain either:

(1) Information justifying the requested exemption from the requirement, or

(2) A description of a proposed alternative method of meeting the requirement.

(c) *Criteria for granting an exemption or alternative.* The Director may grant an exemption or alternative if he or she finds that such action is consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable diseases and that:

(1) The information submitted justifies an exemption; or

(2) The proposed alternative satisfies the purpose of the requirement.

(d) *Form of request.* You must ordinarily make your request for an exemption or alternative in writing (hard copy or electronically). However, if circumstances make it difficult (e.g., there is inadequate time) to submit your request in writing, you may make the request orally, and the Director may orally grant an exemption or alternative. You must follow your oral request with an immediate written request, to which the Director will respond in writing.

(e) *Operation under exemption or alternative.* You must not begin operating under the terms of a requested exemption or alternative until the exemption or alternative has been granted. You may apply for an extension of an exemption or alternative beyond its expiration date, if any.

(f) *Documentation.* If you operate under the terms of an exemption or alternative, you must maintain documentation of:

(1) FDA's grant of the exemption or alternative, and

(2) The date on which you began operating under the terms of the exemption or alternative.

(g) *Issuance of an exemption or alternative by the Director.* In a public health emergency, the Director may issue an exemption from, or alternative to, any requirement in part 1271. The Director may issue an exemption or alternative under this section if the exemption or alternative is necessary to assure that certain HCT/Ps will be available in a specified location to respond to an unanticipated immediate need for those HCT/Ps.

§ 1271.160 Establishment and maintenance of a quality program.

(a) *General.* If you are an establishment that performs any step in the manufacture of HCT/Ps, you must establish and maintain a quality program intended to prevent the introduction, transmission, or spread of communicable diseases through the manufacture and use of HCT/Ps. The quality program must be appropriate for the specific HCT/Ps manufactured and the manufacturing steps performed. The quality program must address all core CGTP requirements listed in § 1271.150(b).

(b) *Functions.* Functions of the quality program must include:

(1) Establishing and maintaining appropriate procedures relating to core CGTP requirements, and ensuring compliance with the requirements of § 1271.180 with respect to such procedures, including review, approval, and revision;

(2) Ensuring that procedures exist for receiving, investigating, evaluating, and documenting information relating to core CGTP requirements, including complaints, and for sharing any information pertaining to the possible contamination of the HCT/P or the potential for transmission of a communicable disease by the HCT/P with the following:

(i) Other establishments that are known to have recovered HCT/Ps from the same donor;

(ii) Other establishments that are known to have performed manufacturing steps with respect to the same HCT/P; and

(iii) Relating to consignees, in the case of such information received after the HCT/P is made available for distribution, shipped to the consignee, or administered to the recipient, procedures must include provisions for assessing risk and appropriate followup, and evaluating the effect this information has on the HCT/P and for the notification of all entities to whom the affected HCT/P was distributed, the quarantine and recall of the HCT/P, and/or reporting to FDA, as necessary.

(3) Ensuring that appropriate corrective actions relating to core CGTP requirements, including reaudits of deficiencies, are taken and documented, as necessary. You must verify corrective actions to ensure that such actions are effective and are in compliance with CGTP. Where appropriate, corrective actions must include both short-term action to address the immediate problem and long-term action to prevent the problem's recurrence. Documentation of corrective actions must include, where appropriate:

(i) Identification of the HCT/P affected and a description of its disposition;

(ii) The nature of the problem requiring corrective action;

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(iii) A description of the corrective action taken; and

(iv) The date(s) of the corrective action.

(4) Ensuring the proper training and education of personnel involved in activities related to core CGTP requirements;

(5) Establishing and maintaining appropriate monitoring systems as necessary to comply with the requirements of this subpart (e.g., environmental monitoring);

(6) Investigating and documenting HCT/P deviations and trends of HCT/P deviations relating to core CGTP requirements and making reports if required under § 1271.350(b) or other applicable regulations. Each investigation must include a review and evaluation of the HCT/P deviation, the efforts made to determine the cause, and the implementation of corrective action(s) to address the HCT/P deviation and prevent recurrence.

(c) *Audits.* You must periodically perform for management review a quality audit, as defined in § 1271.3(gg), of activities related to core CGTP requirements.

(d) *Computers.* You must validate the performance of computer software for the intended use, and the performance of any changes to that software for the intended use, if you rely upon the software to comply with core CGTP requirements and if the software either is custom software or is commercially available software that has been customized or programmed (including software programmed to perform a user defined calculation or table) to perform a function related to core CGTP requirements. You must verify the performance of all other software for the intended use if you rely upon it to comply with core CGTP requirements. You must approve and document these activities and results before implementation.

§ 1271.170 Personnel.

(a) *General.* You must have personnel sufficient to ensure compliance with the requirements of this part.

(b) *Competent performance of functions.* You must have personnel with the necessary education, experience, and training to ensure competent perform-

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ance of their assigned functions. Personnel must perform only those activities for which they are qualified and authorized.

(c) *Training.* You must train all personnel, and retrain as necessary, to perform their assigned responsibilities adequately.

§ 1271.180 Procedures.

(a) *General.* You must establish and maintain procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps. You must design these procedures to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of HCT/Ps.

(b) *Review and approval.* Before implementation, a responsible person must review and approve these procedures.

(c) *Availability.* These procedures must be readily available to the personnel in the area where the operations to which they relate are performed, or in a nearby area if such availability is impractical.

(d) *Standard procedures.* If you adopt current standard procedures from another organization, you must verify that the procedures meet the requirements of this part and are appropriate for your operations.

§ 1271.190 Facilities.

(a) *General.* Any facility used in the manufacture of HCT/Ps must be of suitable size, construction, and location to prevent contamination of HCT/Ps with communicable disease agents and to ensure orderly handling of HCT/Ps without mix-ups. You must maintain the facility in a good state of repair. You must provide lighting, ventilation, plumbing, drainage, and access to sinks and toilets that are adequate to prevent the introduction, transmission, or spread of communicable disease.

(b) *Facility cleaning and sanitation.* (1) You must maintain any facility used in the manufacture of HCT/Ps in a clean, sanitary, and orderly manner, to prevent the introduction, transmission, or spread of communicable disease.

(2) You must dispose of sewage, trash, and other refuse in a timely, safe, and sanitary manner.

(c) *Operations*. You must divide a facility used in the manufacture of HCT/Ps into separate or defined areas of adequate size for each operation that takes place in the facility, or you must establish and maintain other control systems to prevent improper labeling, mix-ups, contamination, cross-contamination, and accidental exposure of HCT/Ps to communicable disease agents.

(d) *Procedures and records*. (1) You must establish and maintain procedures for facility cleaning and sanitation for the purpose of preventing the introduction, transmission, or spread of communicable disease. These procedures must assign responsibility for sanitation and must describe in sufficient detail the cleaning methods to be used and the schedule for cleaning the facility.

(2) You must document, and maintain records of, all cleaning and sanitation activities performed to prevent contamination of HCT/Ps. You must retain such records 3 years after their creation.

§ 1271.195 Environmental control and monitoring.

(a) *Environmental control*. Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents, you must adequately control environmental conditions and provide proper conditions for operations. Where appropriate, you must provide for the following control activities or systems:

- (1) Temperature and humidity controls;
- (2) Ventilation and air filtration;
- (3) Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations; and
- (4) Maintenance of equipment used to control conditions necessary for aseptic processing operations.

(b) *Inspections*. You must inspect each environmental control system periodically to verify that the system, including necessary equipment, is adequate and functioning properly. You must take appropriate corrective action as necessary.

(c) *Environmental monitoring*. You must monitor environmental conditions where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents. Where appropriate, you must provide environmental monitoring for microorganisms.

(d) *Records*. You must document, and maintain records of, environmental control and monitoring activities.

§ 1271.200 Equipment.

(a) *General*. To prevent the introduction, transmission, or spread of communicable diseases, equipment used in the manufacture of HCT/Ps must be of appropriate design for its use and must be suitably located and installed to facilitate operations, including cleaning and maintenance. Any automated, mechanical, electronic, or other equipment used for inspection, measuring, or testing in accordance with this part must be capable of producing valid results. You must clean, sanitize, and maintain equipment according to established schedules.

(b) *Procedures and schedules*. You must establish and maintain procedures for cleaning, sanitizing, and maintaining equipment to prevent malfunctions, contamination or cross-contamination, accidental exposure of HCT/Ps to communicable disease agents, and other events that could reasonably be expected to result in the introduction, transmission, or spread of communicable diseases.

(c) *Calibration of equipment*. Where appropriate, you must routinely calibrate according to established procedures and schedules all automated, mechanical, electronic, or other equipment used for inspection, measuring, and testing in accordance with this part.

(d) *Inspections*. You must routinely inspect equipment for cleanliness, sanitation, and calibration, and to ensure adherence to applicable equipment maintenance schedules.

(e) *Records*. You must document and maintain records of all equipment maintenance, cleaning, sanitizing, calibration, and other activities performed in accordance with this section. You

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must display records of recent maintenance, cleaning, sanitizing, calibration, and other activities on or near each piece of equipment, or make the records readily available to the individuals responsible for performing these activities and to the personnel using the equipment. You must maintain records of the use of each piece of equipment, including the identification of each HCT/P manufactured with that equipment.

§ 1271.210 Supplies and reagents.

(a) *Verification.* You must not use supplies and reagents until they have been verified to meet specifications designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases. Verification may be accomplished by the establishment that uses the supply or reagent, or by the vendor of the supply or reagent.

(b) *Reagents.* Reagents used in processing and preservation of HCT/Ps must be sterile, where appropriate.

(c) *In-house reagents.* You must validate and/or verify the processes used for production of in-house reagents.

(d) *Records.* You must maintain the following records pertaining to supplies and reagents:

(1) Records of the receipt of each supply or reagent, including the type, quantity, manufacturer, lot number, date of receipt, and expiration date;

(2) Records of the verification of each supply or reagent, including test results or, in the case of vendor verification, a certificate of analysis from the vendor; and

(3) Records of the lot of supply or reagent used in the manufacture of each HCT/P.

§ 1271.215 Recovery.

If you are an establishment that recovers HCT/Ps, you must recover each HCT/P in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

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§ 1271.220 Processing and process controls.

(a) *General.* If you are an establishment that processes HCT/Ps, you must process each HCT/P in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

(b) *Pooling.* Human cells or tissue from two or more donors must not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing.

(c) *In-process control and testing.* You must ensure that specified requirements, consistent with paragraph (a) of this section, for in-process controls are met, and that each in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received and documented. Sampling of in-process HCT/Ps must be representative of the material to be evaluated.

(d) *Dura mater.* (1) When there is a published validated process that reduces the risk of transmissible spongiform encephalopathy, you must use this process for dura mater (or an equivalent process that you have validated), unless following this process adversely affects the clinical utility of the dura mater.

(2) When you use a published validated process, you must verify such a process in your establishment.

§ 1271.225 Process changes.

Any change to a process must be verified or validated in accordance with § 1271.230, to ensure that the change does not create an adverse impact elsewhere in the operation, and must be approved before implementation by a responsible person with appropriate knowledge and background. You must communicate approved changes to the appropriate personnel in a timely manner.

§ 1271.230 Process validation.

(a) *General.* Where the results of processing described in § 1271.220 cannot be fully verified by subsequent inspection

and tests, you must validate and approve the process according to established procedures. The validation activities and results must be documented, including the date and signature of the individual(s) approving the validation.

(b) *Written representation.* Any written representation that your processing methods reduce the risk of transmission of communicable disease by an HCT/P, including but not limited to, a representation of sterility or pathogen inactivation of an HCT/P, must be based on a fully verified or validated process.

(c) *Changes.* When changes to a validated process subject to paragraph (a) of this section occur, you must review and evaluate the process and perform revalidation where appropriate. You must document these activities.

§ 1271.250 Labeling controls.

(a) *General.* You must establish and maintain procedures to control the labeling of HCT/Ps. You must design these procedures to ensure proper HCT/P identification and to prevent mix-ups.

(b) *Verification.* Procedures must include verification of label accuracy, legibility, and integrity.

(c) *Labeling requirements.* Procedures must ensure that each HCT/P is labeled in accordance with all applicable labeling requirements, including those in §§ 1271.55, 1271.60, 1271.65, 1271.90, 1271.290, and 1271.370, and that each HCT/P made available for distribution is accompanied by documentation of the donor eligibility determination as required under § 1271.55.

§ 1271.260 Storage.

(a) *Control of storage areas.* You must control your storage areas and stock rooms to prevent:

(1) Mix-ups, contamination, and cross-contamination of HCT/Ps, supplies, and reagents, and

(2) An HCT/P from being improperly made available for distribution.

(b) *Temperature.* You must store HCT/Ps at an appropriate temperature.

(c) *Expiration date.* Where appropriate, you must assign an expiration date to each HCT/P based on the following factors:

(1) HCT/P type;

(2) Processing, including the method of preservation;

(3) Storage conditions; and

(4) Packaging.

(d) *Corrective action.* You must take and document corrective action whenever proper storage conditions are not met.

(e) *Acceptable temperature limits.* You must establish acceptable temperature limits for storage of HCT/Ps at each step of the manufacturing process to inhibit the growth of infectious agents. You must maintain and record storage temperatures for HCT/Ps. You must periodically review recorded temperatures to ensure that temperatures have been within acceptable limits.

§ 1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.

(a) *Receipt.* You must evaluate each incoming HCT/P for the presence and significance of microorganisms and inspect for damage and contamination. You must determine whether to accept, reject, or place in quarantine each incoming HCT/P, based upon pre-established criteria designed to prevent communicable disease transmission.

(b) *Predistribution shipment.* If you ship an HCT/P within your establishment or between establishments (e.g., procurer to processor) and the HCT/P is not available for distribution as described in paragraph (c) of this section, you must first determine and document whether pre-established criteria designed to prevent communicable disease transmission have been met, and you must ship the HCT/P in quarantine.

(c) *Availability for distribution.* (1) Before making an HCT/P available for distribution, you must review manufacturing and tracking records pertaining to the HCT/P, and, on the basis of that record review, you must verify and document that the release criteria have been met. A responsible person must document and date the determination that an HCT/P is available for distribution.

(2) You must not make available for distribution an HCT/P that is in quarantine, is contaminated, is recovered from a donor who has been determined

to be ineligible or for whom a donor-eligibility determination has not been completed (except as provided under §§ 1271.60, 1271.65, and 1271.90), or that otherwise does not meet release criteria designed to prevent communicable disease transmission.

(3) You must not make available for distribution any HCT/P manufactured under a departure from a procedure relevant to preventing risks of communicable disease transmission, unless a responsible person has determined that the departure does not increase the risk of communicable disease through the use of the HCT/P. You must record and justify any departure from a procedure at the time of its occurrence.

(d) *Packaging and shipping.* Packaging and shipping containers must be designed and constructed to protect the HCT/P from contamination. For each type of HCT/P, you must establish appropriate shipping conditions to be maintained during transit.

(e) *Procedures.* You must establish and maintain procedures, including release criteria, for the activities in paragraphs (a) through (d) of this section. You must document these activities. Documentation must include:

(1) Identification of the HCT/P and the establishment that supplied the HCT/P;

(2) Activities performed and the results of each activity;

(3) Date(s) of activity;

(4) Quantity of HCT/P subject to the activity; and

(5) Disposition of the HCT/P (e.g., identity of consignee).

(f) *Return to inventory.* You must establish and maintain procedures to determine if an HCT/P that is returned to your establishment is suitable to be returned to inventory.

§ 1271.270 Records.

(a) *General.* You must maintain records concurrently with the performance of each step required in this subpart and subpart C of this part. Any requirement in this part that an action be documented involves the creation of a record, which is subject to the requirements of this section. All records must be accurate, indelible, and legible. The records must identify the person performing the work and the dates

of the various entries, and must be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular HCT/P involved.

(b) *Records management system.* You must establish and maintain a records management system relating to core CGTP requirements. Under this system, records pertaining to a particular HCT/P must be maintained in such a way as to facilitate review of the HCT/Ps history before making it available for distribution and, if necessary, subsequent to the HCT/Ps release as part of a followup evaluation or investigation. Records pertinent to the manufacture of HCT/Ps (e.g., labeling and packaging procedures, and equipment logs) must also be maintained and organized under the records management system. If records are maintained in more than one location, then the records management system must be designed to ensure prompt identification, location, and retrieval of all records.

(c) *Methods of retention.* You may maintain records required under this subpart electronically, as original paper records, or as true copies such as photocopies, microfiche, or microfilm. Equipment that is necessary to make the records available and legible, such as computer and reader equipment, must be readily available. Records stored in electronic systems must be backed up.

(d) *Length of retention.* You must retain all records for 10 years after their creation, unless stated otherwise in this part. However, you must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/Ps distribution, disposition, or expiration, whichever is latest. You must retain records for archived specimens of dura mater for 10 years after the appropriate disposition of the specimens.

(e) *Contracts and agreements.* You must maintain the name and address and a list of the responsibilities of any establishment that performs a manufacturing step for you. This information must be available during an inspection conducted under § 1271.400.

§ 1271.290 Tracking.

(a) *General.* If you perform any step in the manufacture of an HCT/P in which you handle the HCT/P, you must track each such HCT/P in accordance with this section, to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action.

(b) *System of HCT/P tracking.* (1) You must establish and maintain a system of HCT/P tracking that enables the tracking of all HCT/Ps from:

(i) The donor to the consignee or final disposition; and

(ii) The consignee or final disposition to the donor.

(2) Alternatively, if you are an establishment that performs some but not all of the steps in the manufacture of an HCT/P in which you handle the HCT/P, you may participate in a system of HCT/P tracking established and maintained by another establishment responsible for other steps in the manufacture of the same HCT/P, provided that the tracking system complies with all the requirements of this section.

(c) *Distinct identification code.* As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Except as described in § 1271.55(a)(1), you must create such a code specifically for tracking, and it may not include an individual's name, social security number, or medical record number. You may adopt a distinct identification code assigned by another establishment engaged in the manufacturing process, or you may assign a new code. If you assign a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the old code.

(d) *Tracking from consignee to donor.* As part of your tracking system, you must establish and maintain a method for recording the distinct identifica-

tion code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor.

(e) *Tracking from donor to consignee or final disposition.* As part of your tracking system, you must establish and maintain a method for documenting the disposition of each of your HCT/Ps, to enable tracking from the donor to the consignee or final disposition. The information you maintain must permit the prompt identification of the consignee of the HCT/P, if any.

(f) *Consignees.* At or before the time of distribution of an HCT/P to a consignee, you must inform the consignee in writing of the requirements in this section and of the tracking system that you have established and are maintaining to comply with these requirements.

(g) *Requirements specific to dura mater donors.* You must archive appropriate specimens from each donor of dura mater, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible spongiform encephalopathy, and to enable appropriate disposition of any affected nonadministered dura mater tissue, if necessary.

[69 FR 68681, Nov. 24, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 1271.320 Complaint file.

(a) *Procedures.* You must establish and maintain procedures for the review, evaluation, and documentation of complaints as defined in § 1271.3(aa), relating to core current good tissue practice (CGTP) requirements, and the investigation of complaints as appropriate.

(b) *Complaint file.* You must maintain a record of complaints that you receive in a file designated for complaints. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint (including the distinct identification code of the HCT/P that is the subject of the complaint) and for determining whether the complaint is an isolated event or represents a trend. You must make the complaint file available for review and copying upon request from FDA.

(c) *Review and evaluation of complaints.* You must review and evaluate each complaint relating to core CGTP requirements to determine if the complaint is related to an HCT/P deviation or to an adverse reaction, and to determine if a report under §1271.350 or another applicable regulation is required. As soon as practical, you must review, evaluate, and investigate each complaint that represents an event required to be reported to FDA, as described in §1271.350. You must review and evaluate a complaint relating to core CGTP requirements that does not represent an event required to be reported to determine whether an investigation is necessary; an investigation may include referring a copy of the complaint to another establishment that performed manufacturing steps pertinent to the complaint. When no investigation is made, you must maintain a record that includes the reason no investigation was made, and the name of the individual(s) responsible for the decision not to investigate.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

SOURCE: 69 FR 68686, Nov. 24, 2004, unless otherwise noted.

§ 1271.330 Applicability.

The provisions set forth in this subpart are being implemented for non-reproductive HCT/Ps described in §1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and for the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.350 Reporting.

(a) *Adverse reaction reports.* (1) You must investigate any adverse reaction involving a communicable disease related to an HCT/P that you made available for distribution. You must report

to FDA an adverse reaction involving a communicable disease if it:

- (i) Is fatal;
- (ii) Is life-threatening;
- (iii) Results in permanent impairment of a body function or permanent damage to body structure; or
- (iv) Necessitates medical or surgical intervention, including hospitalization.

(2) You must submit each report on a Form FDA-3500A to the address in paragraph (a)(5) of this section within 15 calendar days of initial receipt of the information.

(3) You must, as soon as practical, investigate all adverse reactions that are the subject of these 15-day reports and must submit followup reports within 15 calendar days of the receipt of new information or as requested by FDA. If additional information is not obtainable, a followup report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained.

(4) You may obtain copies of the reporting form (FDA-3500A) from the Center for Biologics Evaluation and Research (see address in paragraph (a)(5) of this section). Electronic Form FDA-3500A may be obtained at <http://www.fda.gov/medwatch> or at <http://www.hhs.gov/forms>.

(5) You must submit two copies of each report described in this paragraph to the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. FDA may waive the requirement for the second copy in appropriate circumstances.

(b) *Reports of HCT/P deviations.* (1) You must investigate all HCT/P deviations related to a distributed HCT/P for which you performed a manufacturing step.

(2) You must report any such HCT/P deviation relating to the core CGTP requirements, if the HCT/P deviation occurred in your facility or in a facility that performed a manufacturing step for you under contract, agreement, or other arrangement. Each report must contain a description of the HCT/P deviation, information relevant to the event and the manufacture of the HCT/P involved, and information on all follow-up actions that have been or will

be taken in response to the HCT/P deviation (e.g., recalls).

(3) You must report each such HCT/P deviation that relates to a core CGTP requirement on Form FDA-3486 available at <http://www.fda.gov/cber/biodev/bpdrform.pdf>, within 45 days of the discovery of the event either electronically at <http://www.fda.gov/cber/biodev/biodevsub.htm> or by mail to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (HFM-600), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

§ 1271.370 Labeling.

The following requirements apply in addition to §§ 1271.55, 1271.60, 1271.65, and 1271.90:

(a) You must label each HCT/P made available for distribution clearly and accurately.

(b) The following information must appear on the HCT/P label:

(1) Distinct identification code affixed to the HCT/P container, and assigned in accordance with § 1271.290(c);

(2) Description of the type of HCT/P;

(3) Expiration date, if any; and

(4) Warnings required under § 1271.60(d)(2), § 1271.65(b)(2), or § 1271.90(b), if applicable and physically possible. If it is not physically possible to include these warnings on the label, the warnings must, instead, accompany the HCT/P.

(c) The following information must either appear on the HCT/P label or accompany the HCT/P:

(1) Name and address of the establishment that determines that the HCT/P meets release criteria and makes the HCT/P available for distribution;

(2) Storage temperature;

(3) Other warnings, where appropriate; and

(4) Instructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases.

[69 FR 68686, Nov. 24, 2004, as amended at 70 FR 29952, May 25, 2005]

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

SOURCE: 69 FR 68687, Nov. 24, 2004, unless otherwise noted.

§ 1271.390 Applicability.

The provisions set forth in this subpart are applicable only to HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and to the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.400 Inspections.

(a) If you are an establishment that manufactures HCT/Ps described in § 1271.10, whether or not under contract, you must permit the Food and Drug Administration (FDA) to inspect any manufacturing location at any reasonable time and in a reasonable manner to determine compliance with applicable provisions of this part. The inspection will be conducted as necessary in the judgment of the FDA and may include your establishment, facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers, and controls required to be maintained under the part. The inspection may be made with or without prior notification and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) FDA will call upon the most responsible person available at the time of the inspection of the establishment and may question the personnel of the establishment as necessary to determine compliance with the provisions of this part.

(d) FDA's representatives may take samples, may review and copy any records required to be kept under this part, and may use other appropriate

means to record evidence of observations during inspections conducted under this subpart.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of HCT/Ps will be handled in accordance with FDA's procedures on disclosure of information as set forth in parts 20 and 21 of this chapter.

§ 1271.420 HCT/Ps offered for import.

(a) Except as provided in paragraphs (c) and (d) of this section, when an HCT/P is offered for import, the importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part, and must provide sufficient information for FDA to make an admissibility decision.

(b) Except as provided in paragraphs (c) and (d) of this section, an HCT/P offered for import must be held intact by the importer or consignee, under conditions necessary to prevent transmission of communicable disease, until an admissibility decision is made by FDA. The HCT/P may be transported under quarantine to the consignee, while the FDA district reviews the documentation accompanying the HCT/P. When FDA makes a decision regarding the admissibility of the HCT/P, FDA will notify the importer of record.

(c) This section does not apply to reproductive HCT/Ps regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and donated by a sexually intimate partner of the recipient for reproductive use.

(d) This section does not apply to peripheral blood stem/progenitor cells regulated solely under section 361 of the Public Health Service Act and the regulations in this part, except that paragraphs (a) and (b) of this section apply when circumstances occur under which such imported peripheral blood stem/progenitor cells may present an unreasonable risk of communicable

disease transmission which indicates the need to review the information referenced in paragraph (a) of this section.

§ 1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

(a) Upon an agency finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in this part and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission; or the HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission, the Food and Drug Administration (FDA) may take one or more of the following actions:

(1) Serve upon the person who distributed the HCT/P a written order that the HCT/P be recalled and/or destroyed, as appropriate, and upon persons in possession of the HCT/P that the HCT/P must be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the HCT/P is confirmed;

(2) Take possession of and/or destroy the violative HCT/P; or

(3) Serve upon the establishment an order to cease manufacturing until compliance with the regulations of this part has been achieved. When FDA determines there are reasonable grounds to believe there is a danger to health, such order will be effective immediately. In other situations, such order will be effective after one of the following events, whichever is later:

(i) Passage of 5 working days from the establishment's receipt of the order; or

(ii) If the establishment requests a hearing in accordance with paragraph (e) of this section and part 16 of this chapter, a decision in, and in accordance with, those proceedings.

(b) A written order issued under paragraph (a) of this section will state with

particularity the facts that justify the order.

(c)(1) A written order issued under paragraph (a)(1) of this section will ordinarily provide that the HCT/P be recalled and/or destroyed within 5 working days from the date of receipt of the order. After receipt of an order issued under paragraph (a)(1) of this section, the establishment in possession of the HCT/P must not distribute or dispose of the HCT/P in any manner except to recall and/or destroy the HCT/P consistent with the provisions of the order, under the supervision of FDA.

(2) In lieu of paragraph (c)(1) of this section, other arrangements for assuring the proper disposition of the HCT/P may be agreed upon by the person receiving the written order and FDA. Such arrangements may include, among others, providing FDA with records or other written information that adequately ensure that the HCT/P has been recovered, processed, stored, and distributed in conformance with this part, and that, except as provided under §§ 1271.60, 1271.65, and 1271.90, the donor of the cells or tissue for the HCT/P has been determined to be eligible.

(d) A written order issued under paragraph (a)(3) of this section will specify the regulations with which you must achieve compliance and will ordinarily specify the particular operations cov-

ered by the order. After receipt of an order that is in effect and issued under paragraph (a)(3) of this section, you must not resume operations without prior written authorization of FDA.

(e) The recipient of an order issued under this section may request a hearing in accordance with part 16 of this chapter. To request a hearing, the recipient of the written order or prior possessor of such HCT/P must make the request within 5 working days of receipt of a written order for retention, recall, destruction, and/or cessation (or within 5 working days of the agency's possession of an HCT/P under paragraph (a)(2) of this section), in accordance with part 16 of this chapter. An order of destruction will be held in abeyance pending resolution of the hearing request. Upon request under part 16 of this chapter, FDA will provide an opportunity for an expedited hearing for an order of cessation that is not stayed by the Commissioner of Food and Drugs.

(f) FDA will not issue an order for the destruction of reproductive tissue under paragraph (a)(1) of this section, nor will it carry out such destruction itself under paragraph (a)(2) of this section.

PARTS 1272–1299 [RESERVED]